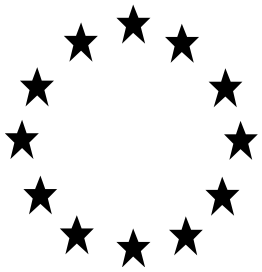
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS

(submitted by the evaluating Competent Authority)



Montplet Insect repellent IR3535 30%

Product type(s) 19

IR3535 as included in the Union list of approved active substances

Case Number in R4BP: BC-RX020604-13

Evaluating Competent Authority: Spain

October 2023

Table of Contents

1 CONCLUSION

Physical-chemical properties and Analytical Methods

MONTPLET INSECT REPELLENT IR3535 30% is a colourless liquid with a pleasant odour. Its pH is 4.99 at 1% diluted.

The formulation has shown to be stable under accelerated conditions (30°C during 18 weeks) and after storing at 25°C for 3 years. Thus, a self-life of 3 years is granted. Due to the fact that the low temperature test has not been carried out the biocidal products have to be protected from frost.

Furthermore, it is not considered to be explosive, oxidising or pyrophoric. But the bridged result of flash point (32°C) from Montplet insect repellent IR3535 20% show that the product is flammable. Therefore, according to CLP Regulation, it has to be categorized as flammable liquid cat.3 (H226).

The analytical methods provided are fully validated for the determination of the active substancs, Ethyl butylacetylaminopropionate, IR3535®. Methods for the determination of the residues are available in the CAR of the active substances.

Conclusion on efficacy

The product MONTPLET INSECT REPELLENT IR3535 30% is efficient as a mosquito repellent for 6 hours in tropical and temperate conditions when applied on skin at the application rate of 0.56 mg product / cm^2.

Conclusion on human health

MONTPLET INSECT REPELLENT IR3535 30% can be authorized following Art.19(1) of Regulation (EU) No 528/2012 as a ready-to-use repellent (PT19) in temperate and tropical areas and should only be applied once per day on uncovered parts of the face, hands, arms, legs and feet.

The applicant submits a human health risk assessment (HHRA) for MONTPLET INSECT REPELLENT IR3535 30% in line with the latest agreements reached at UE level. This HHRA, as performed by the applicant, concludes that the biocidal product pose risk for human health with regard to the intended uses. For children 2-6 years, toddler and infant users there is risk, therefore its use will not be authorized for this subpopulations. MONTPLET INSECT REPELLENT IR3535 30% should not be applied for children below 6 years. At the time of submission, neither the Commission implementing Decision (EU) 2018/1477 nor the Recommendation no. 11 of the BPC Ad hoc Working Group on Human Exposure for harmonizing the assessment of human exposure to repellents (18 January 2018) were available. The assessment has been updated the assessment in order to include the latest agreements on this matter.

It should be noted that the HHRA has been calculated using a efficacy tests dose (0.56 mg/cm^2) obtained from the efficacy data, which has proved to be efficacious during the protection time for each climate zone. This conclusion is in line with the Commission implementing Decision (EU) 2018/1477 on the terms and conditions of the authorisations of biocidal products containing ethyl butylacetylaminopropionate.

Environment

Based on this risk assessment and on available data, «Montplet Insect repellent IR3535 30%» should not cause any unacceptable risks to the environment.

2 ASSESSMENT REPORT

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product

Identifier	Country (if relevant)
MONTPLET INSECT REPELLENT IR3535 30% ACOFARMA NESIRA REPELENTE DE INSECTOS FORTE APOSAN REPELENTE DE INSECTOS FORTE BIOVECTROL REPELENTE DE INSECTOS EXTREME COMPO BARRERA REPELENTE DE INSECTOS XTREM CUIDAPLUS REPELENTE DE INSECTOS FORTE DDERMA REPELENTE DE INSECTOS FORTE DELIPLUS REPELENTE DE INSECTOS FUERTE DEXIN ANTIMOSQUITOS EXTREM PLUS REPELENTE DE INSECTOS HALLEY REPELENTE DE INSECTOS FORTE INTERAPOTHEK REPELENTE DE INSECTOS FUERTE MONTPLET REPELENTE DE INSECTOS FORTE NORMOPIC REPELENTE DE INSECTOS FORTE KITAPIC REPELENTE DE INSECTOS FORTE NEWELL ANTIMOSQUITOS FORTE PARASITAL REPELENTE DE INSECTOS FORTE PERFUM PROTECT FORTE REPELENTE DE INSECTOS NOSA-KIT REPELENTE DE INSECTOS FORTE REPEL BITE REPELENTE DE INSECTOS FORTE	SPAIN

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	Laboratorios Montplet, S.L.U.
	Address	Via Trajana 53-59 08020 – Barcelona - Spain
Authorisation number	ES/APP(NA)-2023-19-00902	
Date of the authorisation	Xx/10/2023	
Expiry date of the authorisation	XX/10/2033	

2.1.1.3 Manufacturer(s) of the product

Name of manufacturer	Laboratorios Montplet, S.L.U.
Address of manufacturer	Via Trajana 53-59 08020 – Barcelona
Location of manufacturing sites	Via Trajana 53-59 08020 – Barcelona

2.1.1.4 Manufacturer(s) of the active substance(s)

Active substance	Ethyl butylacetylaminopropionate
Name of manufacturer	Merck KGaA
Address of manufacturer	Frankfurter Strase 250 64293 Darmstadt Germany
Location of manufacturing sites	Polígono Merck 08100 Mollet de Valles Barcelona Spain

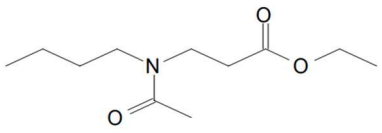
2.1.2 Product composition and formulation

NB: the full composition of the product according to Annex III Title 1 should be provided in the confidential annex.

Does the product have the same identity and composition as the product evaluated in connection with the approval for listing of the active substance(s) on the Union list of approved active substances under Regulation No. 528/2012?

Yes X
No ☐

2.1.2.1 Identity of the active substance

Main constituent(s)	
ISO name	Ethyl butylacetylaminopropionate, IR3535®
IUPAC or EC name	3-(N-acetyl-N-butyl)aminopropionic acid ethyl ester
EC number	257-835-0
CAS number	52304-36-6
Index number in Annex VI of CLP	None
Minimum purity / content	≥ 990 g/kg
Structural formula	

2.1.2.2 Candidate(s) for substitution

The active substance contained in the biocidal formulation of biocidal single product "Montplet Insect repellent IR3535 30% "is not a candidate for substitution in accordance with Article 10 of BPR

2.1.2.3 Qualitative and quantitative information on the composition of the biocidal product

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Ethyl butylacetylaminopropionate, IR3535®	3-(N-acetyl-N-butyl)aminopropionic acid ethyl ester	Active substance	52304-36-6	257-835-0	30.00

For the complete qualitative and quantitative information on final composition of the biocidal single product, please refer to the confidential annex of this document.

2.1.2.4 Information on technical equivalence

The source of Ethyl butylacetylaminopropionate, IR3535® is the same as was evaluated for inclusion in the Union list of approved active substance, therefore is not considered equivalent to the Union list of approved active substance source.

2.1.2.5 Information on the substance(s) of concern

No substances of concern were identified in the formulation.

2.1.2.6 Type of formulation

AL – Any other liquid

2.1.3 Hazard and precautionary statements[1]

Classification and labelling of the product according to the Regulation (EC) 1272/2008

Classification	
Hazard category	Flam. Liquid 3 Eye irrit. 2
Hazard statement	H226: Flammable liquid and vapour H319: Causes serious eye irritation
Labelling	
Signal words	Warning
Hazard statements	H226: Flammable liquid and vapour H319: Causes serious eye irritation
Precautionary statements	P101: If medical advice is needed, have product container or label at hand P102: Keep out of reach of children P103: Read label before use. P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P233: Keep container tightly closed. P264: Wash hands thoroughly after handling. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337+P313: If eye irritation persists: Get medical advice/attention.
Note	

2.1.4 Authorised use(s)

2.1.4.1 Use description

Table 1. Use # 1 – Mosquitoes repellent – spray to apply on human skin – General public

Product Type	PT19 – Repellents and attractants (Pest control)

Where relevant, an exact description of the authorised use	Repellent against mosquitoes in temperate and tropical areas.
Target organism (including development stage)	Scientific name: Culicidae Common name: Mosquitoes (Culex spp., Aedes spp., Anopheles spp) Development stage: Adults
Field of use	Indoor use in well ventilated areas Outdoor
Application method(s)	Spraying Apply on the skin zones to be protected. Do not spray the product directly on the face. Apply the product over the body with the hand. Do not apply on children's hands. Frequent and repeated application of this product is unnecessary.
Application rate(s) and frequency	Application rate: 0.56 mg/cm^2 of skin area to be protected*. Adults: 5.11 g or aprox. 27 pump strokes Children (6-<12 years): 2.83 g or aprox. 15 pump strokes **Do not use in children younger than 6 years old.** Frequency of application: Only one application/day Protection time against mosquitoes: 6 hours In temperate and tropical areas. This product is **not intended to be reapplied**.
Category(ies) of users	General public (Non-professional)
Pack sizes and packaging material	HDPE spray bottle (trigger spray) of the following volumes: 50ml ; 75ml; 100 ml; 125ml; 150 ml; 200 ml; 250 ml and 500 ml

*Dischargre/spray rate = 0.1949 ml (Applicant data)

2.1.4.1.1 Use-specific instructions for use

- Apply and spread evenly on the skin zones to protect (arms, hands, legs, feet and face).
- Adults: 27 spray pump a day (5 on arm, 12 on leg, 5 on the face, 1 on hands and 4 on feet)
- Children (6-<12 years): 15 spray pump a day (3 on arm, 8 on leg, 2 on the face, 2 on feet)
- Spray directly on the exposed skin and distribute the liquid with the hand. Do not spray the product directly on the face, but applied with hands, avoiding contact with mouth and eyes. Wash your hands thoroughly after applying the product.
- Once the time of protection is over properly wash the body area where the product has been applied

- CHILDREN MUST NOT APPLY THIS PRODUCT. An adult should apply the product on children. Do not apply on children's hands. Do not apply over cuts, wounds, freshly shaven or irritated skin. Do not use under clothing. Do not use in children younger than 6 years. If necessary, consult your pediatrician.
- Frequent and repeated application of this product is unnecessary
- The use of the product with other repellent products is not recommended.
- If the product is to be used in combination with sunscreen lotion, first apply the sunscreen lotion and wait 30 minutes before applying the product.
- This repellent is authorized for temperate and tropical areas.The protection time is only indicative. Environmental factors (e.g. high temperature, wind velocity, exposure to water) can modify it.

2.1.4.1.2 Use-specific risk mitigation measures

- Always read the label and product information before use. Avoid breathing the spray.
- Use only outdoors or in well ventilated areas.
- Do not swallow.
- Avoid breathing vapours/spray.
- Do not use on children’s hands.
- For children of 6 to 12 years: the repellent must be applied by adults.
- Keep out of reach of children.
- Do not use near food and surfaces that may come into contact with food and feed or drinks for human consumption and animal feedingstuffs.
- Avoid contact of the treated skin with food and feed.
- Do not use near domestic animals.
- Do not use in people sensitive to its components.
- Keep the container upright.

2.1.4.1.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

See general directions for use

2.1.4.1.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

See general directions for use

2.1.4.1.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

See general directions for use

2.1.5 General directions for use

2.1.5.1 Instructions for use

See section 2.1.4.1.1

Comply with the instructions for use:
- Before use the product, read carefully the label. The instructions above should be followed.
- Apply sparingly and spread evenly a thin layer on the uncovered skin (face, hands, arms, legs and feet) to be protected. Repeated application of this product not authorized.
- Do not throw the product on the ground, into a water course, into the sink or down the drain
- Inform the registration holder if the treatment is ineffective.

2.1.5.2 Risk mitigation measures

See section 2.1.4.1.2

2.1.5.3 Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.
IF SWALLOWED: Rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call a POISON CENTRE or a doctor

IF ON SKIN: Wash skin with water. Only the part of the skin that were not supposed to be exposed should be washed. If irritation occurs the skin should be washed and medical advice should be sought.

IF IN EYES: Rinse with water. Remove contact lenses, if present and easy to do. Continue rinsing for 5 minutes. Call a POISON CENTRE or a doctor.

IF MEDICAL ADVICE IS NEEDED, HAVE THE PRODUCT CONTAINER OR LABEL AT HAND AND CONTACT THE POISON CONTROL CENTER

For Enviroment:

- Use for repellent purpose only. Once this purpose has been fulfilled, discard properly to avoid its release to the environment.

2.1.5.4 Instructions for safe disposal of the product and its packaging

- Empty containers should be deposited in separate collection containers according to the material of the containers.
- Unused product and other waste generated during the treatment must be deposited in the residual fraction or in the collecting facilities.

2.1.5.5 Conditions of storage and shelf-life of the product under normal conditions of storage

- Keep out of reach of children and non target animals/pets

- Protect from frost.
- Store the product at temperature lower than 30°C
- Shelf life: 36 months.

2.1.6 Other information

General public (non-professional user): Users who are not professionals and who apply the product in the context of their private life.

2.1.7 Packaging of the biocidal product

Type of packaging	Size/volume of the packaging	Material of the packaging	Type and material of closure(s)	Intended user (e.g. professional, non-professional)	Compatibility of the product with the proposed packaging materials (Yes/No)
Spray bottle	50ml ; 75ml; 100 ml; 125ml; 150 ml; 200 ml; 250 ml; 500 ml*	HDPE, recycled HDPE or PET bottle	multimaterial Spray pump (spray dose 200 µl) Cap of the spray nozzle in LDPE.	Non-professional	Yes

*ES will apply the art 37 in order to limit the maximum size of packaging until 200ml according to national risk mitigation measures of the use of repellents by non-professional user

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

No new data on the active substance itself or on the substances of concern has been submitted in function of this product application. All new information relates to the biocidal product described within this application.

2.1.8.2 Access to documentation

The applicant has submitted a Letter of Access for the active substance from Merck KGaA as owner data for active substance.

2.2 Assessment of the biocidal product

2.2.1 Intended use(s) as applied for by the applicant

Table 2. Intended Use # 1 – Mosquitoes repellent – spray to apply on human skin – General public

Product Type	PT19

Where relevant, an exact description of the authorised use	Repellent
Target organism (including development stage)	Scientific name: *Culicidae* Common name: Mosquitoes *(Culex spp. Aedes spp., Anopheles spp.)* Development stage: Adults
Field of use	Outdoor and indoor use in well ventilated areas Use in tropical and temperate areas.
Application method(s)	Spraying Apply sparingly and spread evenly a thin layer on the uncovered skin (face, hands, arms, legs and feet) to be protected. Spray directly on the exposed skin and distribute the liquid with the hand. Do not spray directly to the face.
Application rate(s) and frequency	Application rate: Up to 1 application per day. **<u>Do not use in children younger than 6 years old.</u>** Dose per application: 0.56 mg/cm² Application rate: • Adults: 27 spray pumps • Children 6-12y: 15 spray pumps Protection time against mosquitoes: - up to 6 hours against Aedes mosquitoes - up to 7 hours against Culex mosquitoes This product is **not intended to be reapplied**.
Category(ies) of users	General public.
Pack sizes and packaging material	HDPE, recycled HDPE, PET spray bottle (trigger spray) of the following volumes: 50ml ; 75ml; 100 ml; 125ml; 150 ml; 200 ml; 250 ml and 500 ml

2.2.2 Physical, chemical and technical properties

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Physical state at 20 °C and 101.3 kPa	Visual	Montplet insect repellent IR3535 30%	Liquid	Report nº 2017/201 AM (2020)
Colour at 20 °C and 101.3 kPa	Visual	Montplet insect	Transparent liquid colourless	Report nº 2017/201 AM (2020)

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
		repellent IR3535 30%		
Odour at 20 °C and 101.3 kPa	Not guideline followed	Montplet insect repellent IR3535 30%	Pleasant odour	Report nº 2017/201 AM (2020)
pH Acidity / alkalinity	CIPAC MT 75.3	Montplet insect repellent IR3535 30%	pH (1%) = 4.99 pH = 3.89 (After long term storage at ambient temperature) Acidity average result: 0,034% +/- 0,004 The pH decreases by more than 1 point during the 3 years of the product's shelf life. This decrease is due to the generation of the degradation product of IR3535, its free acid which is generated by hydrolysis during the shelf life of the product.	Report nº 2017/201 AM (2020)
Relative density / bulk density	OECD 109	Montplet insect repellent IR3535 30%	0.9709 at 20.0 ºC	Report nº 2017/201 AM (2020)
Storage stability test – **accelerated storage**	CIPAC method MT 46.3	Montplet insect repellent IR3535 30%	Temperature 30 ºC (18 weeks) The appearance of the commercial packaging (HDPE) and the weight of the test item in the commercial packaging did not change significantly. IR3535 (% w/w) T_0: 29.244% T_{18w}: 29.855% (+2.09%)< 10%	Report nº 2017/200 AM (2018)
Storage stability test – **long term storage at ambient temperature**	CropLife International, Technical Monograph No. 17	Montplet insect repellent IR3535 30%	Temperature 25 °C/60% RH (36 months) Weight loss at time: - T_0: - - T_{6M}: 0.25% - T_{12M}: 0.23% - T_{18M}: 0.82% - T_{24M}: 0.94%	Report nº 2017/201 AM (2020)

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			- T_{30M}: 1.50% - T_{36M}: 1.42% Active substance content: T_0: 29.440% w/w T_{6M}: 29.526% w/w Δ[C]: +0.29% < 10% T_0: 29.440% w/w T_{12M}: 29.826% w/w Δ[C]: +1.31% < 10% T_0: 29.440% w/w T_{18M}: 29.500% w/w Δ[C]: +0.20% < 10% T_0: 29.440% w/w T_{24M}: 29.592% w/w Δ[C]: +0.52% < 10% T_0: 29.440% w/w T_{30M}: 29.775% w/w Δ[C]: +1.14% < 10% T_0: 29.440% w/w T_{36M}: 28.747% w/w Δ[C]: -2.35% < 10% Results show that the product is stable after 36 months at ambient temperature. The appearance of the packaging (HDPE) : no variation from initial • Valve clogging for T_0; T_{6M}; T_{12M}; T_{18M}; T_{24M}; T_{30M}; T_{36M}: - No clogging Spray pattern : T_0: Like a spray T_{36M} No significant variation Particle size distribution T_0: Dv (50) = 63.6 µm T_{36M}: Dv (50)=72.93µm	
Storage stability test – **low**	Waiver	No testing is necessary as it is indicated on the product label that it should be protected from cold.		

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
temperature stability test for liquids				
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	Waiver	No testing is necessary because the packaging is opaque and therefore protects the product from light.		
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	The effect of temperature was assessed in the accelerated storage study and the results were acceptable. However, it has been added the sentence "Store the product at temperatures lower than 30°C" since it is the maximum temperature at which the stability has been assessed. The product is protected from humidity thanks to its impermeable packaging.			
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	Visual	Montplet insect repellent IR3535 30%	At initial time, the packaging was white plastic bottle (HDPE) with trigger dispenser and no variation has been observed after storing. So no reactivity towards container has been remarked by the laboratory.	2017/201 AM (2020)
Wettability	Waiver	Not relevant		
Suspensibility, spontaneity and dispersion stability	Waiver	Not relevant		
Wet sieve analysis and dry sieve test	Waiver	Not relevant		
Emulsifiability, re-emulsifiability and emulsion stability	Waiver	Not relevant		
Disintegration time	Waiver	Not relevant		

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Particle size distribution, content of dust/fines, attrition, friability	CIPAC MT 187	Montplet insect repellent IR3535 30%	Dv (50) = 63.6 µm (Natural fluted spray pump with transparent cover) Please refer to the Confidential Annex for more information about the packaging.	Report nº 2017/201 AM (2020)
Persistent foaming	Waiver	Not relevant		
Flowability/Pourability/Dustability	Waiver	Not relevant		
Burning rate — smoke generators	Waiver	Not relevant		
Burning completeness — smoke generators	Waiver	Not relevant		
Composition of smoke — smoke generators	Waiver	Not relevant		
Discharge/spray rate	FEA 643	Montplet insect repellent IR3535 30%	0.16 g	Report nº 2017/201 AM (2020)
Spraying pattern — aerosols	FEA 644	Montplet insect repellent IR3535 30%	Like a spray. (Natural fluted spray pump with transparent cover) Please refer to the Confidential Annex for more information about the packaging.	Report nº 2017/201 AM (2020)
Valve clogging	According to FAO	Montplet insect repellent IR3535 30%	No clogging	Report nº 2017/201 AM (2020)
Physical and Chemical compatibility	Not relevant because the product is not intended to be used in combination with any other product.			
Degree of dissolution and dilution stability	Waiver	Not relevant		
Surface tension	EC method A.5	Montplet insect	31.12 mN/m at	Report nº IN-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
		repellent IR3535 30%		01232/2020 -3 (2020)
Viscosity	Rotational viscosimeters	Montplet insect repellent IR3535 30%	Dynamic viscosity: 27.5 mPa.s at 20 ºC 15.4 mPa.s at 40 ºC	Report nº19-0328.03 (2019)

Conclusion on the physical, chemical and technical properties of the product
The product "Montplet Insect Repellent IR3535 30%" is a AL (Any other liquid) product. All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is a transparent liquid colourless. There is no effect of high temperature on the stability of the formulation, since after 18 weeks at 30 ºC, neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of at least 3 years at ambient temperature. Its technical characteristics are acceptable for an AL formulation.

2.2.3 Physical hazards and respective characteristics

Please note the following data on flammable liquids hazard is directly bridged from the results obtained in the studies conducted on the formulations ”Montplet insect repellent IR3535 20%”. Indeed, the percentage of alcohol in the Montplet Insect repellent IR3535 30% is lower than in the reference product (23.7% w/w in the "Montplet Insect repellent IR3535 30%" vs. 33% w/w in the "Montplet insect repellent IR3535 20%"). The "Montplet insect repellent IR3535 20%" is therefore considered to be a worst-case product and its flash-point is expected to be higher than the one of the product defended in this dossier. Please find the proposed waiver comparing the composition of both products in the section 3.7.2 of this dossier (Confidential annex).

In the same way, please note the following data on auto-ignition properties is bridged from the study of Merck conducted on the product "Merck Insect repellent IR3535 20%”. This formulation has a similar composition of the product defended in this dossier. In addition, the Merck’s formulation covers the Montplet formulation in terms of ethanol content. Please find the proposed waiver comparing the composition of both products in the section 3.7.1 of this dossier (Confidential annex).

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Explosives	Waived	Explosive properties are associated with the presence of certain chemical functional groups in the molecule which can react to produce very rapid increases in temperature and/or pressure. As explained in the CLP Criteria Guidance and Appendix 6, Section 5.1 of the UN-MTC., the screening procedure is aimed at		

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
		identifying the presence of such reactive groups and the potential for rapid energy release in order to avoid unnecessary testing. The characteristic groups which present explosive properties are: – C-C unsaturation (e.g. acetylenes, acetylides, 1, 2-dienes); – C-Metal, N-Metal (e.g. Grignard reagents, organo-lithium compounds); – Contiguous nitrogen atoms (e.g. azides, aliphatic azo compounds, diazonium salts, hydrazines, sulphonylhydrazides); – Contiguous oxygen atoms (e.g. peroxides, ozonides); – N-O (e.g. hydroxyl amines, nitrates, nitro compounds, nitroso compounds, N-oxides, 1,2-oxazoles); – N-halogen (e.g. chloramines, fluoroamines); – O-halogen (e.g. chlorates, perchlorates, iodosyl compounds). None of the co-formulants in the biocidal product contains any of these chemical groups in their structure thus none of the substances, and consequently the mixture, are not considered to present explosive properties.		
Flammable gases	Waived	The product is a liquid formulation.		
Flammable aerosols	Waived	The product is a liquid formulation.		
Oxidising gases	Waived	The product is a liquid formulation.		
Gases under pressure	Waived	The product is a liquid formulation.		
Flammable liquids	ASTM method D-93	Montplet insect repellent IR3535 20%	The tested product Montplet insect repellent IR3535 20% contains circa 10% more of ethanol than the biocidal product Montplet insect repellent IR3535 30% and presents a flashpoint of 32ºC. It could be expected that product Montplet insect repellent IR3535 30% flammable properties would be lower than those extrapolated from the reference product data. However, it can be concluded from published data and internal data from other	Report nº 3634437 (2002) (Read across)

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			ethanol-based formulas, that even 10% ethanol solutions present flash points between 23 and 60ºC which would classify the product as H226. Therefore, the product needs to be classified as 'flammable liquid' (H226).	
Flammable solids	Waived	The product is a liquid formulation.		
Self-reactive substances and mixtures	Waived	Self-reactive substances are, for example, some compounds of the types listed below: – Aliphatic azo compounds (-C-N=N-C-); – Organic azides (-C-N3); – Diazonium salts (-CN2 +Z -); – N-nitroso compounds (-N-N=O); and – Aromatic sulfohydrazides (-SO2-NH-NH2) This list is not exhaustive and substances with other reactive groups, combination of groups and some mixtures of substances may have similar properties. Additional guidance on substances, which may have self-reactive properties, is given in Appendix 6, Section 5.1 of the UN-MTC. None of the co-formulants in the biocidal product contains any of these chemical groups in their structure thus none of the substances, and consequently the mixture, are not considered to present self-reactive properties.		
Pyrophoric liquids	Waived	None of the ingredients are classified as pyrophoric substances.		
Pyrophoric solids	Waived	The product is a liquid formulation.		
Self-heating substances and mixtures	Waived	None of the ingredients are classified as self-heating substances.		
Substances and mixtures which in contact with water emit flammable gases	Waived	None of the ingredients are classified as able to emit flammable gases in contact with water.		
Oxidising liquids	Waived	None of the ingredients are classified as oxidising substances.		
Oxidising solids	Waived	The product is a liquid formulation.		
Organic peroxides	Waived	None of the ingredients are classified as organic peroxides.		
Corrosive to metals	UN Manual Test 37.4	Montplet Insect repellent	No corrosion attack was occurred after 7 days of	Report nº 21/01067 (2021)

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
		IR3535 30%	exposure at the temperature of 55 ºC.	
Auto-ignition temperatures of products (liquids and gases)	EC A15 auto-ignition	Merck Insect Repellent IR3535 20%	Auto-ignition temperature = 440°C	Report nº 242-002 (2011) (Read across)
Relative self-ignition temperature for solids	Waived	The product is a liquid formulation.		
Dust explosion hazard	Waived	The product is a liquid formulation.		

Conclusion on the physical hazards and respective characteristics of the product

The conducted test complies with requirements for determining the flash point of flammable liquids (Pensky-Martens method). For the biocidal product "Montplet insect repellent IR3535 30%" the results on flammable liquid study bridged from the "Montplet insect repellent IR3535 20%" formulation show a flash point value of 32°C. This result is higher than 23°C and lower than 60°C, concluding that the formulation should be classified as a flammable liquid category 3 (H226) according to CLP Criteria, Version 5.0 (July 2017).

Furthermore, please note that the data on auto-ignition property are directly bridged from the results obtained in the study conducted on the Merk's formulation "Merck Insect Repellent IR3535 20%". The percentage of alcohol in the "Montplet Insect repellent IR3535 30%" is lower than in the reference product. This study show an auto-ignition temperature = 440°C which does not conclude to any auto-ignition hazard at the temperatures at which the product is used or transported

2.2.4 Methods for detection and identification

Analyte (type of analyte e.g. active substance)	Analytical method	Fortification range / Number of measurements	Linearity	Specificity	Recovery rate (%)			Reference
					Range	Mean	RSD	
Ethyl butylacetylaminopropionate (IR3535®)	HPLC-UV	Linearity: - 5 calibration solutions Precision: - 6 samples Accuracy: - 3 different concentrations (50% – 150%), three levels, two preparations for each level	Range: 15.0% w/w-45.0% w/w corresponding to experimental range 50%-150% of the theoretical value in the sample y=68.6879 + 2672.3594x R^2= 0.9997	The method proved to be specific: no peak of blank or placebo solution interfered with that of the active ingredient	100.58 – 100.87	100.81	0.28	Report nº S-2017-02130 AM (2017)

Conclusion on the methods for detection and identificationof the product
According to guideline SANCO/3030/99 the analytical methods provided are fully validated for the determination of the active substance, Ethyl butylacetylaminopropionate, IR3535®.

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

Product Type 19: Repellents and attractants (pest control).
According to the SPC submitted by the applicant, the product **Montplet insect repellent IR3535 30 %** is intended to be used by general public in temperate and tropical areas.

2.2.5.2 Organisms to be controlled and products, organisms or objects to be protected

According to the use claimed by the applicant:

- The product **Montplet insect repellent IR3535 30 %** is intended to be used to repel insects on skin.
- The target organisms to be controlled are mosquitoes.
- The organisms to be protected are humans.

2.2.5.3 Effects on target organisms, including unacceptable suffering.

Montplet insect repellent IR3535 30 % is intended to be used as an insect repellent from mosquitoes (Aedes sp., Culex sp. and Anopheles sp.) by application on skin.

The efficacy of **Montplet insect repellent IR3535 30 %** has been demonstrated against mosquitoes.

2.2.5.4 Mode of action, including time delay

The mode of action of IR3535® is not a passive masking of an attracting odour of a victim, but an active repellent effect as insects avoid entering regions with IR3535® vapours. According to the Competent Authority Report of Ethyl butylaceylaminopropionate (Belgium, 2014), the exact biochemical mode of action of IR3535® on insects is not well known yet, but it is most self-evident to assume that IR3535® has an olfactory-based effect.

2.2.5.5 Efficacy data

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Repellent	- Spray - Applied on human skin -For consumers -In temperate and tropical areas	Montplet insect repellent IR3535 30%	*MOSQUITOES Aedes albopictus, Culex pipiens* and *Anopheles gambiae* Female, 5-7 days old, starved from blood-meal for 12 hours before testing	Simulated use test. Arm-in-cage study. Acording to ECHA Guidance on the BPR: Volume II Parts B+C Version 4.0 December 2021	- 100+/-2 females in the 64 L cages - Dose of product 0,56 mg/cm² of skin (i.e. 0,34 g/600 cm² forearm). - 10 volunteers (10 unit tests) - Minimun landing rate for control: *Aedes albopictus* 20 landings/minute ; *Culex pipiens* 5 landings/minute ; *Anopheles gambiae* 5 landings/minute - Exposure started 1 min after application. The duration of exposure of the treated forearm in the cage was 3 minutes. - Each test (control + test) was repeated every hour until the first landing and then every 30 minutes until proven inefficacy of the product. - Temperate climatic conditions: Temperature 27±2 °C Relative humidity 75 ±5 %	After application of the product at dose 0,56 mg/cm² of skin, the duration of protection was 6 hours for *Aedes albopictus*, 7 hours for *Culex pipiens* and 7 hours for *Anopheles gambiae.* Temperate and tropical areas.	[redacted] **Reliability 1** **Key study**

Conclusion on the efficacy of the product
The efficacy study submitted demonstrates that: The product MONTPLET INSECT REPELLENT IR3535 30% is efficient as a mosquito repellent (Aedes albopictus for 6 hours, Culex pipiens for 7 hours and Anopheles gambiae for 7 hours) in tropical and temperate areas when applied on skin at the application rate of 0,56 mg product / cm². **The product MONTPLET INSECT REPELLENT IR3535 30% is efficient as a mosquito repellent for 6 hours in tropical and temperate conditions when applied on skin at the application rate of 0,56 mg product / cm².**

2.2.5.6 Occurrence of resistance and resistance management

The following statement from the assessment report of the active substance applies to the product "Montplet insect repellent IR3535 30%": "as the active substance, IR3535, is a repellent (no killing action) and does not give rise to selection pressure, no resistance can be developed".

2.2.5.7 Known limitations

N.D.

2.2.5.8 Evaluation of the label claims

Efficacy against mosquitoes has been assessed with several mosquito species. According to the Guidance on BPR: Volume II (parts B+C), efficacy tests should be performed with Culex, Aedes and Anopheles mosquitoes to support a claim in temperate and tropical areas.

Efficacy studies have proven the efficacy of the product "Montplet insect repellent IR3535 30%".

2.2.5.9 Relevant information if the product is intended to be authorised for use with other biocidal product(s)

The product "Montplet insect repellent IR3535 30%" is not intended to be used with other biocidal products.

2.2.6 Risk assessment for human health

The representative product considered in the Competent Authority Report (CAR) from Belgium finalised in the Standing committee on Biocidal Products at its meeting on March 13th, 2014 for IR3535 was a water/ethanol-based 20% IR3535 formulation.

The product "Montplet insect repellent IR3535 30%" is similar to this representative product. The main difference between «Montplet insect repellent IR3535 30%» and the representative product is the content of IR3535 which is 30% in «Montplet insect repellent IR3535 30%» and 20% in representative product. The other ingredients are the same in both products with slightly different contents.

2.2.6.1 Assessment of effects on Human Health

An eye irritation study was conducted with a representative product, which contains 20% of IR3535.The applicant confirms that is identical to Montplet insect repellent IR3535 20% The report does not indicate if the study is generated according to the Good Laboratory Practices, and not establish any level for reliability. ES CA doesn't validate this test

An acute dermal toxicity study was conducted with product which contains 30% of IR3535 .The applicant confirms that is identical to Montplet insect repellent IR3535 30%

When no experimental toxicological data on the preparation (or on a product which composition is known and similar) was available, the toxicological classification for this mixture was carried out by using the conventional calculation method of the Regulation (EC) No. 1272/2008~1221/2015 (CLP).

Skin corrosion and irritation

In product «Montplet insect repellent IR3535 30%», there are no ingredient classified for their skin corrosion/irritation properties.
Testing on the product does not need to be conducted as synergistic effects between components are not expected.

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Not skin corrosive. Not skin irritant
Justification for the value/conclusion	Based on the classification of IR3535 and its respective content in the final formulation.
Classification of the product according to CLP and DSD	Not classified

Data waiving	
Information requirement	**Skin corrosion and irritation**
Justification	There are valid data available on each of the components in the product Montplet insect repellent IR3535 30% are sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP Regulation), and synergistic effects between any of the components are not expected. In the product, there are no ingredient classified for their skin corrosion/irritation properties.

Eye irritation

An eye irritation study was conducted with a representative product, which contains 20% of IR3535. The report does not specify if the test complies with OECD norm 405. However, the methodology followed is equivalent to OECD norm 405 The report does not indicate if the study is generated according to the Good Laboratory Practices and and not establish any level for reliability. ES CA doesn't validate this test

So, the toxicological classification for this mixture has carried out by using the conventional calculation method of the Regulation (EC) No. 1272/2008~1221/2015 (CLP).

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Eye irritant.
Justification for the value/conclusion	Based on the classification of the IR3535, the coformulants and, their respective content in the final formulation
Classification of the product according to CLP and DSD	Eye irritant, Category 2 - H319.

Data waiving	
Information requirement	Eye irritation study
Justification	ES CA does not validate the submitted test for not following the GLP criteria and for not establishing any level for reliability. So, the

	classification of the mixture according to the rules laid down in Regulation (EC) Nº 1272/2008 (CLP Regulation),10% is the concentration triggering the classification of a skin irritant category 2 in a mixture. Therefore, based on the concentration of the active substance and co-formulants, the product Montplet insect repellent IR3535 30% is classified as Eye irritant. 2; H319 .

Respiratory tract irritation

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Justification for the conclusion	No ingredient classified.
Classification of the product according to CLP and DSD	Not classified.

Data waiving	
Information requirement	Respiratory tract irritation.
Justification	The active substance IR3535 showed no irritant properties to the respiratory tract in animals or in humans. In product «Montplet insect repellent IR3535 30%», there are no ingredient classified for their respiratory tract irritant properties.

Skin sensitization

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Not skin sensitizer
Justification for the value/conclusion	Based on the classification of the IR3535 and the different co-formulants and, their respective content in the final formulation.
Classification of the product according to CLP and DSD	Not classified.

Data waiving	
Information requirement	Skin sensitisation study
Justification	Testing on the product does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected. Therefore, based on the classification of the active substance and coformulants, the product Montplet insect repellent IR3535 30% is not classified as skin sensitizer So this study does not need to be conducted.

	The fragrance is classified skin sens 1; H317. However as the relevant components for skin sensitisation are well below of their concentration limits for elicitation, EUH208 must not be included.

Respiratory sensitization (ADS)

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Not respiratory sensitizer.
Justification for the value/conclusion	Based on the classification of the IR3535 and the different co-formulants and, their respective content in the final formulation.
Classification of the product according to CLP and DSD	Not classified

Data waiving	
Information requirement	Respiratory sensitization data
Justification	No data on the respiratory sensitisation of the product Montplet insect repellent IR3535 30% has been submitted However, the biocidal product is not expected to have respiratory sensitizing properties since none of the components of the mixture shows respiratory sensitisation effects.

Acute toxicity

Acute toxicity by oral route

Value used in the Risk Assessment – Acute oral toxicity	
Value	None
Justification for the selected value	In product «Montplet insect repellent IR3535 30%», there are no ingredient classified for their acute oral toxic properties and no synergistic effects between components are expected.
Classification of the product according to CLP and DSD	Not classified

Data waiving	
Information requirement	Acute oral toxicity studies
Justification	Acute oral toxicity studies for product «Montplet insect repellent IR3535 30%» have not been performed. There aren´t ingredient classified for their acute oral toxic properties. So, it is therefore proposed that the product «Montplet insect repellent IR3535 30%», is not harmful by the oral route and will remain unclassified following criteria of the Regulation (EC) Nº 1272/2008 (CLP Regulation).

Acute toxicity by inhalation

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	None
Justification for the selected value	In product «Montplet insect repellent IR3535 30%», there are no ingredient classified for their acute inhalation potential and no synergistic effects between components are expected.
Classification of the product according to CLP and DSD	Not classified

Data waiving	
Information requirement	Acute inhalation toxicity studies
Justification	Acute inhalation toxicity studies for product «Montplet insect repellent IR3535 30%» have not been performed. There aren´t ingredient classified for their acute inhalation toxicity. The biocidal product can be considered as no toxic by the inhalation route according to Regulation (EC) Nº 1272/2008.

Acute toxicity by dermal route

A study was conducted with a representative product, which contains 30% of IR3535.The applicant confirms that It is Montplet insect repellent IR3535 30%.

Test complies with OECD 402. The report indicate that the study is generated according to the Good Laboratory Practices and with a reability of 1.

Summary table of animal studies on acute dermal toxicity						
Method, Guideline, GLP status, Reliability	**Species, strain, Sex, No/group**	**Test substance, Vehicle, Dose levels, Surface area**	**Signs of toxicity** *(nature, onset, duration, severity, reversibility)*	**LD50**	**Remarks** *(e.g. major deviations)*	**Reference**
Acute dermal toxicity, OECD 402, GLP, RL: 1	Rat, SD, 5 males and 5 females	Montplet insect repellent IR3535 30% ,no vehicle, 2000 mg/kg bw, 10% of total body surface	None	>2000 mg/kg bw	None	Freli V. (2012) Study No.2012/1085 AMi (Report 70)

No human data available.

Value used in the Risk Assessment – Acute dermal toxicity	
Value	LD50 >2000 mg/kg bw

Justification for the selected value	Reliable study conducted on the product. This study showed that «Montplet insect repellent IR3535 30%» has a dermal LD50 >2000 mg/kg bw.
Classification of the product according to CLP and DSD	Not classified

Data waiving	
Information requirement	Acute dermal toxicity studies
Justification	Acute dermal toxicity studies for product «Montplet insect repellent IR3535 30%» have been performed. This study showed that «Montplet insect repellent IR3535 30%» is not acutely toxic dermal because your LD50 >2000 mg/kg bw according to Regulation (EC) Nº 1272/2008. The biocidal product can be considered as no toxic by the inhalation route

Information on dermal absorption

No study (*in vivo* or *in vitro*) has been performed with Montplet insect repellent IR3535 30%.
A read across with the dermal absorption value of 14%, proposed in the study of Dekant et al. 2010 has been proposed by the applicant. The results of this study have been summarized in the CAR of active substance and were assessed for the approval of IR3535®
5 male and 5 female volunteers sprayed approx. 3g of a formulation containing 20% IR3535 onto hands, arms, feet, legs, neck, face (50% of total body area) and showered 12 hours after application. The total amount of IR3535® and its metabolite IR3535®-free acid excreted with the urine over a period of 48 hours presented 13.3% of the dermal dose of IR3535® applied. Since IR3535® is rapidly and extensively metabolized and as IR3535®- free acid has a low molecular weight and high water solubility, it is expected that urinary excretion of IR3535®-free acid and IR3535® represents the total extent of absorption of IR3535® in humans and a distribution to organs and issues is considered to be negligible. The data of this study suggest that most absorption takes place in the first 6 hours after application with no further evidence of absorption beyond this time point. Based on these findings, a dermal absorption of 14 % is also valid for an exposure of 24 hours.

Since the composition of 30% IR3535 formulation of MONTPLET INSECT REPELLENT IR3535 30% is comparable to the product tested in the dermal toxicokinetics/metabolism study, especially as concerns the content of organic solvents and emulsifiers/surfactants which may have an impact on the skin absorption, a separate skin absorption study with the biocidal product is not considered to be required. Instead, the skin absorption of 14% for IR3535® as decided in the Assessment Report for IR3535 can be applied to the 30% IR3535 farmulation of MONTPLET INSECT REPELLENT IR3535 30%. Therefore, a dermal penetration of 14% could be used in the human exposure assessment of the biocidal product.

On the other hand, according to Guidance on Dermal Absorption (EFSA 2012) the rate of absorption is generally inversely related to the concentration of the active substance. For this reason, the skin absorption of IR3535 from the 30% IR3535 formulation of Montplet insect repellent IR3535 30% will be very likely lower than 14% therefore, the use of the skin absorption as derived in the dermal toxicokinetics/metabolism study represents a conservative approach.

However, taking into account that the read across with the dermal absorption value of 14% proposed in the study of Dekant et al. 2010of has been widely used by other Member States in the evaluation of IR3535-repellent biocide products, ES CA accepts this value for risk assessment. Nevertheless, ES CS considers that at the renewal stage of the active substance, this value should be revised.

Value used in the Risk Assessment – Dermal absorption	
Substances	IR3535®
Value	14%
Justification for the selected value	Worst case value reported in CAR

Data waiving	
Information requirement	Dermal absorption
Justification	According to EFSA guidance 2012 criteria since the composition of 30% IR3535 formulation of MONTPLET INSECT REPELLENT IR3535 30% is comparable to the product tested (20% IR3535) in the dermal toxicokinetics/metabolism study, especially as concerns the content of organic solvents and emulsifiers/surfactants which may have an impact on the skin absorption, a separate skin absorption study with the biocidal product is not considered to be required. Therefore, the skin absorption of 14% for IR3535® as decided in the Assessment Report for IR3535 20% can be applied to the 30% IR3535 farmulation of MONTPLET INSECT REPELLENT IR3535 30%. Therefore, a dermal penetration of 14% could be used in the human exposure assessment of the biocidal product.

Endocrine disrupting properties

Since 7 June 2018, date when the Regulation (EU) 2017/2100 came into force, endocrine disrupting properties assessment of active substance and co-formulants is mandatory according to the article 19 of BPR.
According to the CAR for Ethyl butylacetylaminopropionate (IR3535®) there is no indication for endocrine disrupting properties of the active substance. However, a comprehensive ED-assessment for the active substance and its metabolites according to Regulation (EU) 2017/2100 and the "Revised Guidance Document 150 on Standardised Test Guidelines for Evaluating Chemicals for Endocrine Disruption" will need to be performed at the renewal stage.

After reviewing the potential ED properties of co-formulants (please refer to the Confidential Annex), the biocidal product contains one substance which is under assessment as potential endocrine disruptor in the frame of the Community Rolling Action Plan (CoRAP). However, this evaluation has not been finalised yet. If that substance is identified as having ED properties in the future, the conditions for granting the biocidal product authorisation will be revised. Please, refer to the confidential annex for more information

Available toxicological data relating to non-active substance(s) (i.e. substance(s) of concern)

According to the formulation there is no other potential substance to be classified of concern for human risk with the exception of the active substance. For further details please refer to the Confidential Annex.

Available toxicological data relating to a mixture

No further studies on the toxicity of the product are required as there are valid data available on the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) 1272/2008 (CLP)

2.2.6.2 Exposure assessment

MONTPLET INSECT REPELLENT IR3535 30% is intended to be applied as an insect repellent by spraying on human skin.

The exposure assessment submitted by the applicant is based on the Competent Authority Report (CAR) for IR3535. The representative product considered in the CAR for IR3535 was a water/ethanol-based 20% IR3535 formulation. At the time of submission, neither the Commission implementing Decision (EU) 2018/1477 nor the Recommendation no. 11 of the BPC Ad hoc Working Group on Human Exposure for harmonizing the assessment of human exposure to repellents (18 January 2018) were available. The eCA (evaluating competent authority) has updated the assessment in order to include the latest agreements on this matter.

The exposure has been calculated with the efficacious dose (0.56 mg/cm²) obtained from the data from active substance's supplier.

Identification of main paths of human exposure towards active substance(s) and substances of concern from its use in biocidal product

Summary table: relevant paths of human exposure							
Exposure path	**Primary (direct) exposure**			**Secondary (indirect) exposure**			
	Industrial use	**Professional use**	**Non-professional use**	**Industrial use**	**Professional use**	**General public**	**Via food**
Inhalation	n.a.	n.a.	Yes	n.a.	n.a.	Yes	n.a.
Dermal	n.a.	n.a.	Yes	n.a.	n.a.	Yes	n.a.
Oral	n.a.	no	Yes [1]	n.a.	n.a.	Yes	n.a.

n.a.: not applicable

1- For primary exposure, direct oral exposure is not considered to be relevant since the product is not intended to be applied by children and oral exposure can be precluded among adults with a minimum hygene standards. Despite the latter, the non respirable particles might precipitate in the upper ways and be taken orally. However, since the inhalation absorption considered is a 100%, and no refinement between respirable and non respirable fraction is performed (due to the lack of data), this exposure should be covered

For primary exposure (adult spraying on the skin), the most relevant route of exposure is the dermal route. During the application, inhalation exposure is possible during spraying. It was considered that the respirable particles will be absorbed via the lower airways and that the non-respirable particles will precipitate in the upper airways and be taken in orally. The particles above 5 µm are assumed to be taken in orally. The particles above 5 µm are

assumed to be taken in orally (Technical Notes for Guidance on Human Exposure, Chapter 3.5.2 (page 247)). However, since the inhalation absorption considered is a 100%, and no refinement between respirable and non respirable fraction is performed (due to the lack of data). Direct oral exposure is not considered to be relevant because of the repellent taste (bad palatability) of the active substance and since the product is not intended to be applied by children. Oral exposure can be precluded among adults with a minimum hygiene standard.

For secondary exposure, dermal exposure is possible for an adults applying or spraying the product on children and herself/himself. Hand to mouth transfer is also possible for adults and children; nonetheless, the biocidal product is not intended to be applied on children's hands which reduces potential oral uptake of the dermally applied active substance. For inhalative exposure, the inhalation of volatilized residues after application is also relevant based on the HEEG opinion on Assessment of Inhalation Exposure of Volatilized Biocide Active Substance.

It should be noticed that neither inhalation or oral exposure are expected to be significant routes of exposure; because of the small fraction of respirable particles and the bad palatability (bitterness) of the product which prevents repeated mouthing by small children. Therefore, these scenarios are unlikely and should be considered as worse cases.

In addition, and in order to prevent any potential exposure, the following RMMs are considered:

i. "For children 6 to 12 years: The repellent must be applied by adults"

ii." Do not apply to children's hands"

iii. "Keep out of reach of children"

List of scenarios

Summary table: scenarios			
Scenario number	**Scenario** (e.g. mixing/ loading)	**Primary or secondary exposure Description of scenario**	**Exposed group** (e.g. professionals, non-professionals, bystanders)
1.	Application Spraying	**Primary exposure**. Spraying on the skin. Exposure route: dermal and inhalation	Non-professional
2	Post-application Adult treating or handling children	**Secondary exposure** An adult applying or spraying the product on children and herself/himself. Exposure route: dermal and inhalation	Non-professional
3	Post-application Hand-mouth transfer	**Secondary exposure** Hand to mouth transfer Exposure route: oral	Non-professional General public
4.	Post-application Inhalation of volatilized residues	**Secondary exposure** Inhalation of volatilised residues after application (inhalative exposure) Exposure route: inhalation	Non-professional General public

Industrial exposure

The production of MONTPLET INSECT REPELLENT IR3535 30% is automated and the modelling of exposure and risk assessment/risk characterisation during this production should be addressed under other EU legislation and not repeated here, unless the active substance was totally new to the EU market and manufactured in the EU. This is not the case for ethyl butylacetylaminopropionate (IR3535) which is an existing biocidal active substance within the EU.

Professional exposure

MONTPLET INSECT REPELLENT IR3535 30% will not be used by professional users. Neither primary nor secondary exposure can happen for this population.

Non-professional exposure

MONTPLET INSECT REPELLENT IR3535 30% will be used by non-professional people. Primary and secondary exposure can happen for this population.

The following exposure scenarios are considered:

Scenario 1: Adult spraying on the skin (primary exposure).
Scenario 2: Adult applying the product on children and herself/himself (secondary exposure).

Scenario [1] Adult spraying on the skin (primary exposure)

Description of Scenario [1] Adult spraying on the skin (primary exposure)
It is considered that the exposure of the person spraying the product is covered by the exposure to the product he applies on his skin. MONTPLET INSECT REPELLENT IR3535 30% is applied directly to the intact skin of adults and children. Indoor and outdoor applications are possible. Exposure is expected to happen via the dermal and inhalation routes. The amount of product applied will be considered for the dermal exposure evaluation. The exposure by dermal route can be calculated according to the following equation: $$PDE = \frac{Dp \times C_{IR3535} \times BS \times DA \times N}{100 \times 100 \times BW}$$ where: PDE — Potential dermal exposure (mg/kg b.w./day) D_p — Dose of product applied on skin (mg/cm²) C_{IR3535} — Concentration of substance in product (%) BS — Body surface exposed to the product (cm²) (more information below) DA — Dermal absorption (%) N — Number of product application per day (/day) BW — Body weight (kg) The following data is being considered: amount b.p. is the derived from the efficacy data (0.56 mg/cm²) Percentage of body surface to be treated For adults, in line with the ECHA Recommendation no. 11 "Proposal for harmonising the assessment of human exposure to repellents (PT19)", it is considered that 55% of the

total body surface remains uncovered and is treated with repellent, it will be used to calculate the BS. Indeed, it is assumed that during the whole season (mid-term exposure within a year) a short-sleeved shirt (i.e. T-shirt) and shorts are worn. The product is not sprayed directly on the face, but applied with hands, avoiding contact with mouth and eyes. The hands should be washed after applying the product, but their surface is included nevertheless in the applied surface area.
For infants, toddlers and children in a worst case approach, the same skin exposure percentage as for adults, 55%, is considered to calculate the BS. In a worst case approach, it is 55% of the total body surface, including the hands, that is used even though the hands of infants, toddlers and children are not exposed to the repellent. Indeed, they will not apply the product themselves and the adults should not apply the product to children's hands. Although the applicant initially did not support the use of biocidal product for infants under 1 year of age, a human exposure assessment was still done.

Anthropometric data
The body weights, surface areas and inhalation rates from the ECHA Recommendation no. 14 (Default human factor values for use in exposure assessments for biocidal products) will be used for exposure calculations.
Once the time protection has ended (8-12 hours of efficacy), it is recommended to properly wash the body area where the product has been applied.

For inhalation exposure, the model used is "Consumer spraying and dusting model 2" from TNsG Part 2, p. 197. For a hand-held trigger spray, the 75th percentile value for the inhaled amount is 10.5 mg/m^3.

	Parameters		Value
Tier 1	Concentration of a.s. in the product (no dilution)		30%
	Number of applications per day		1 (for adults, infant, toddler, child from 2 to 12 years old)
	Body weight #	Adult	60 kg
		Infant	8 kg
		Toddler	10 kg
		Child - 2 to <6 years old	15.6 kg
		Child - 6 to <12 years old	23.9 kg
Inhalation	Use duration $		4 min
	Inhalation rate, short-term #	Adult	1.25 m^3/h
		Infant	0.84 m^3/h
		Toddler	1.26 m^3/h
		Child - 2 to <6 years old	1.26 m^3/h
		Child - 6 to <12 years old	1.32 m^3/h
	Inhalation uptake £		100%
Dermal	Dose of product applied on the skin ¤		0.56 mg/cm²
	Dermal uptake		14%
		Adult	9 130 cm²

	55% ¥ of the total body surface area #	Infant	2 255 cm²
		Toddler	2 640 cm²
		Child - 2 to <6 years old	3 740 cm²
		Child - 6 to <12 years old	5 060 cm²

¤ A dose rate of 0.56 mg/cm², is considered on the basis of the data confirmed by Merck. Please refer to the section 3.7.
$ time during which the spraying takes place, i.e. the use duration, from Human exposure to biocidal products (TNsG, part 2 (June 2002), page 256.
# from ECHA Recommendation no. 14 - Default human factor values for use in exposure assessments for biocidal products
¥ from ECHA Recommendation no. 11 - Proposal for harmonising the assessment of human exposure to repellents (PT19)
£ According to the Technical Notes for Guidance on Human Exposure - 2002, Chapter 2.2.3 (page 247) only half of the particles smaller than 5 µm in diameter are respirable for humans. The fraction of particles smaller than 5 µm is probably low in «Montplet insect repellent IR3535 30%».
In the absence of data about the particle size distribution in the product «Montplet insect repellent IR3535 30%», the systemic exposure to IR3535 is calculated as if only from inhalation even if a great part is from the oral route. This has no impact on the final exposure level as the inhalation and the oral absorption rates are both 100%.

Calculations for Scenario [1]

Dermal exposure:

The table below is summarizing the calculation performed with the dose rate of 0.56mg/cm²:

Population group (application)	**Treated body surface area cm²**	**Body weight (kg)**	**Applied product[1] (g)**	**Applied active substance (g)**	**Absorbed active substance (g)**	**Estimated dermal uptake (mg a.s./kg bw/day)**
Adult (1)	9130	60	5.11	1.53	0.21	3.85
Children (6 to <12 years-old) (1)	5060	23.9	2.83	0.85	0.19	4.98
Children (2 to <6 years-old) (1)	3740	15.6	2.09	0.63	0.09	5.64
Toddler (1)	2640	10	1.48	0.44	0.06	6.21
Infant (1)	2255	8	1.26	0.38	0.05	6.63

[1] BS (55% of the total body surface area) x dose rate (0.56 mg/cm²); BS x D_p /1000

Inhalation exposure:
The table below is summarizing the calculation performed with the inhaled product amount of 10.5 mg product/m³:

Population group (application)	Inhaled product per hour (mg/h)	Inhaled product during one application (mg)	Inhaled active substance (mg)	Body weight (kg)	Estimated inhalation uptake (mg a.s./kg bw/day)
Adult (1)	13.16	0.877	0.263	60	0.004
Children (6 to <12 years-old) (1)	13.90	0.926	0.278	23.9	0.012
Children (2 to <6 years-old) (1)	13.26	0.884	0.256	15.6	0.017
Toddler (1)	13.26	0.884	0.265	10	0.026
Infant (1)	8.84	0.590	0.177	8	0.022

Total exposure

Summary table: systemic exposure from non-professional uses					
Exposure scenario		**Estimated inhalation uptake [mg/kg bw d] [1]**	**Estimated dermal uptake [mg/kg bw d]**	**Estimated oral uptake [mg/kg bw d] [1]**	**Estimated total uptake [mg/kg bw d]**
For IR3535®					
Scenario [1]	Adult / 1 spray application/ day	0.004	3. 58	.	**3. 58**
Scenario [1]	Children (6-12 years) / 1 spray application/day	0.012	4.98	.	**4.99**
Scenario [1]	Children (2-6 years) / 1 spray application/day	0.017	5.64	-	**5.66**
Scenario [1]	Toddler (1-2 years) / 1 spray application/day	0.026	6.21	-	**6.24**
Scenario [1]	Infant (< 1 year) / 1 spray application/day	0.022	6.63	-	**6.65**

[1] Part of inhalation uptake (not detailed)

Further information and considerations on scenario [1]
None.

Scenario [2] Adult applying the product on children and herself/himself

Description of Scenario [2] Adult applying the product on children and herself/himself
A worst case is considered with an adult applying the product on two children and herself/himself.

The body weight and inhalation rate from the ECHA Recommendation no. 14 (Default human factor values for use in exposure assessments for biocidal products) will be used for exposure calculations. Exposure is expected to happen via the dermal and inhalation routes. The dermal exposure of the adult is considered to be covered by the general dermal exposure from scenario 1. Regarding inhalation exposure, the time of spraying takes into account 3 times 4 minutes and one application per day. The model used is "Consumer spraying and dusting model 2" from TNsG Part 2, p. 197. For a hand-held trigger spray, the 75th percentile value for the inhaled amount is 10.5 mg/m^3.		
	Parameters	Value
Tier 1	Concentration of a.s. in the product (no dilution)	30%
	Number of applications per person per day	1
	Number of treated person per day	3 (two children and herself/himself)
	Use duration $	4 min
	Adult - inhalation rate, short-term #	1.25 m^3/h
	Inhalation uptake	100%
	Oral uptake	100%
	Adult – body weight #	60 kg

$ time during which the spraying takes place, i.e. the use duration, from Human exposure to biocidal products (TNsG, part 2 (June 2002), page 256.
# from ECHA Recommendation no. 14 - Default human factor values for use in exposure assessments for biocidal products

Calculations for Scenario [2]

Dermal exposure
This is covered by the general dermal exposure of an adult when treating himself/herself (detailed in scenario 1).

Inhalation exposure
The indicative default value of 10.5 mg product/m^3 is considered for inhalation exposure when a hand-held trigger spray is used.

Exposure of the adult treating two children and himself/herself to the product during spraying for 3 times 4 min is calculated according to the inhalation rate:

Adult: 10.5 mg/m^3 x 3 x 4 min x 1.25 m^3/ 60 min = 2.625 mg product per application

According to the Technical Notes for Guidance on Human Exposure - 2002, Chapter 2.2.3 (page 247) only half of the particles smaller than 5 µm in diameter are respirable for humans. The fraction of particles smaller than 5 µm is probably low in MONTPLET INSECT REPELLENT IR3535 30%.

In a worst-case approach, if the absence of data about the particle size distribution in the product MONTPLET INSECT REPELLENT IR3535 30% is considered, the systemic exposure to IR3535 is calculated as if only from inhalation even if a great part is from the oral route. This has no impact on the final exposure level as the inhalation and oral absorption rates are 100%.

Based on one application per day, on the concentration of IR3535 in the product and on 100% absorption, the exposure from inhaled product is:

Adult: 2.625 x 30% x 100% = 0.7875 mg IR3535/day

Inhalation exposure in mg/kg bw/day:
Adult: 0.7875 / 60 = 0.01312 mg IR3535/kg bw/day

Summary table: systemic exposure from non-professional uses – Scenario 2					
Exposure scenario	**Tier/ PPE**	**Estimated inhalation uptake (mg/kg bw/day)**	**Estimated dermal uptake (mg/kg bw/day)**	**Estimated oral uptake (mg/kg bw/day)**	**Estimated total uptake (mg/kg bw/day)**
Scenario [2]	1 / no PPE	0.01312	3.57 (from scenario 1)	Included in inhalation intake	3.59

Further information and considerations on scenario [2]

None.

Combined scenarios

Only adults may be concerned by this combined scenario. Inhalation from scenario 2 covers inhalation from scenario 1 (no addition). As a consequence, exposure under scenario 2 is identical to exposure under combined scenarios 1, 2.

Summary table: combined systemic exposure from non-professional uses				
Scenarios combined	**Estimated inhalation uptake (mg/kg bw/day)**	**Estimated dermal uptake (mg/kg bw/day)**	**Estimated oral uptake (mg/kg bw/day)**	**Estimated total uptake (mg/kg bw/day)**
Scenarios [1,2]	0.01312	3.57	Included in inhalation intake	3.59

Exposure of the general public

The general public can be exposed under secondary exposure scenarios after application of MONTPLET INSECT REPELLENT IR3535 30%.

Those scenarios are:
Scenario 3: Hand to mouth transfer.
Scenario 4: Inhalation of volatilized residues after application indoors.

Scenario [3] Hand to mouth transfer

Description of Scenario [3] Hand to mouth transfer			
Indoor and outdoor applications are possible. Hand to mouth transfer might be possible for small children. However, it is recommended not to apply the product on the hands of children. The bitterness of the product should prevent repeated mouthing due to bad palatability. A reverse reference scenario is considered to determine how much IR3535 anyone can be exposed to after oral exposure without exceeding the reference dose (AEL of 5 mg/kg bw/day). According to TNsG 2002 (Part 2, section 5.2, page 274), the surface of the fingers of an adult represents approximately 4% of the treated dermal surface (not covered by clothes, *i.e.* including head, hands, arms, legs and feet). For a child (or infant or toddler), this surface of possible contact with the mouth represents 10% of the treated dermal surface. The same ratio is considered for infants, toddlers and children whose treated surface also includes the trunk; for them a 10% ratio represents a worst case. The body weights and inhalation rates from the ECHA Recommendation no. 14 (Default human factor values for use in exposure assessments for biocidal products) will be used for exposure calculations. Exposure is expected to happen via the oral route only.			
	Parameters		Value
Tier 1	Concentration of a.s. in the product (no dilution)		30%
	Dose of product applied on the skin ¤		0.56 mg/cm²
	Dose of product per application∞	Adult	5.11 g
		Infant	1.26 g
		Toddler	1.48 g
		Child - 2 to <6 years old	2.09 g
		Child - 6 to <12 years old	2.83 g
	Number of applications per day		1 (for adults, infant, toddler, child from 2 to 12 years old)
	Surface ratio between fingers and the treated surface area $		4% (adults) 10% (child, toddler, infant)
	Oral uptake		100%
	Body weight #	Adult	60 kg
		Infant	8 kg
		Toddler	10 kg
		Child - 2 to <6 years old	15.6 kg
		Child - 6 to <12 years old	23.9 kg

¤ A dose rate of 0.56 mg/cm², is considered on the basis of the data confirmed by Merck. Please refer to the section 3.7.
∞ Please refer to scenario 1 for dose of product per application (=BS x D_p /1000, where the BS correspond to 55% of the total body surface of the corresponding population group and D_p is the dose of product applied on skin)
$ from TNsG 2002, Part 2 section 5.2, page 274.
# from ECHA Recommendation no. 14 - Default human factor values for use in exposure assessments for biocidal products.

Calculations for Scenario [3]

Oral exposure

The external total oral dose of product is calculated per application:

User category	Value				
	Adult	**Children (6-12 years)**	**Children (2-6 years)**	**Toddler (1-2 years)**	**Infant (< 1 year)**
Amount of active substance/application [mg/application]	1533.84	850.08	628.32	443.52	378.84
Body weight [kg]	60	23.9	15.6	10	60
Oral absorption	100	100	100	100	100
Factor for oral intake by hand-mouth transfer	4	10	10	10	10
Oral systemic exposure via hand-mouth transfer mg/kg bw	**1.02**	**2.85**	**3.22**	**3.55**	**3.79**

Total exposure

Summary table: systemic exposure from non-professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake [mg/kg bw d] [1]**	**Estimated dermal uptake [mg/kg bw d]**	**Estimated oral uptake [mg/kg bw d] [1]**	**Estimated total uptake [mg/kg bw d]**
For IR3535®					
Scenario [3]	Adult Tier 1/ no PPE	Not applicable	Not applicable	1.02	**1.02**
Scenario [3]	Children (6-12 years) Tier 1/ no PPE	Not applicable	Not applicable	2.85	**2.85**
Scenario [3]	Children (2-6 years) Tier 1/ no PPE	Not applicable	Not applicable	3.22	**3.22**
Scenario [3]	Toddler (1-2 years) Tier 1/ no PPE	Not applicable	Not applicable	3.55	**3.55**
Scenario [3]	Infant (< 1 years) Tier 1/ no PPE	Not applicable	Not applicable	3.79	**3.79**

Further information and considerations on scenario [3]

None.

Scenario [4] Inhalation of volatilized residues after application indoors

Description of Scenario [4] Inhalation of volatilized residues after application indoors				
For this secondary exposure scenario, inhalation of volatilized residues after indoor application is considered possible. This scenario is included with completeness purposes, since the product is only authorised in well ventilated indoor areas. This scenario is not based on the one available in the CAR of IR3535® because it's has been demonstrated that the SVC could exceed 1% in a number of cases. In the CAR, the assessment is based on the assumption (example calculation in TNsG 2002 part 3, page 50) that the airborne concentration of IR3535 will not exceed 1% of the saturated vapour concentration (SVC). The calculation of the SVC is done on the basis of the physico-chemical properties of IR3535 (from the CAR issued in September 2013). Since that the SVC could exceed the 1% value, the opinion 13 of the HEEG has been taken into account for this scenario. An updated assessment based on ConsExpo: inhalation of vapour, instantaneous release as a worst case has been included according to HEEG opinion. Parameters used for the human exposure scenario are provided in the table below:				
	Parameters			Value
Tier 1	Molecular weight of IR3535			215.29 g/mol
	Vapour pressure of IR3535			0.15 Pa at 20°C, equivalent to $1.5x10^{-3}$ mbar
	Atmospheric pressure			1013 mbar
	Residential time $			24 hours per day
	Room volume			20 m^3
	Temperature			25 ºC
	Parameters for each sub-population[2]	Adult	Inhalation rate	1.25 m^3/h
			Product amount	5112.80 mg
			Body weight	60 kg
		Child - 6 to <12 years old	Inhalation rate	1.32 m^3/h
			Product amount	2833.6 mg
			Body weight	23,9 kg
		Child - 2 to <6 years old	Inhalation rate	1.26 m^3/h
			Product amount	2094.4 mg
			Body weight	15,6 kg
		Toddler	Inhalation rate	1.26 m^3/h
			Product amount	1478.4 mg
			Body weight	10 kg

		Infant	Inhalation rate	0.84 m^3/h
			Product amount	1262.8 mg
			Body weight	8 kg
# from ECHA Recommendation no. 14 - Default human factor values for use in exposure assessments for biocidal products $ from TNsG, part 3 (June 2002), page 50.				

Calculations for Scenario [4]

Inhalation exposure
Inhalation of volatilized residues after application is relevant considering the HEEG opinion 13 on Assessment of Inhalation Exposure of Volatilized Biocide Active Substance (value above 1):

Considering HEEG opinion 13, first a screening test has been performed.

$$\frac{0.328 \times\ 215.29 \times 0.15}{5} = 2.12$$

The result of this equation is superior to 1 which means that the inhalation exposure could not be considered as negligible. So this scenario was assessed using ConsExpo exposure tovapour – instantaneous release according to HEEG opinion 13.

Results for the human exposure scenario using ConsExpo are provide in the table below.

Summary table: systemic exposure from non-professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake [mg/kg bw d] [1]**	**Estimated dermal uptake [mg/kg bw d]**	**Estimated oral uptake [mg/kg bw d] [1]**	**Estimated total uptake [mg/kg bw d]**
For IR3535®					
Scenario [4]	Adult Tier 1/ no PPE	2.66	Not applicable	Not applicable	**2.66**
Scenario [4]	Children (6-12 years) Tier 1/ no PPE	3.91	Not applicable	Not applicable	**3.91**
Scenario [4]	Children (2-6 years) Tier 1/ no PPE	4.22	Not applicable	Not applicable	**4.22**
Scenario [4]	Toddler (1-2 years) Tier 1/ no PPE	4.63	Not applicable	Not applicable	**4.63**
Scenario [4]	Infant (<1 years) Tier 1/ no PPE	3.31	Not applicable	Not applicable	**3.31**

See annex 3.2. for ConsExpo calculations.

Further information and considerations on scenario [4]

Even if based on a worst case basis an SVC approach is deemed inadequate, the continuous exposure during 24 hours is considered quite conservative. Also, it is generally agreed that the inhalation route is excluded due to the use outdoors, and because use indoors takes place in the summer in situations where there is a high ventilation rate. It

should be noticed that the product is only intended to be used in well ventilated facilities. Kindly notice that the product is **only authorised indoors in well ventilated areas .**

For the sake of completeness, the SVC calculations are included below (example calculation in the TNsG on Human exposure, part 3, page 50). From the calculations below if can be concluded that the exposure outdoors and in well ventilated areas is negligible:

The saturated vapour concentration (SVC) is calculated using the following equations:

SVC [ppm] = [vp (substance) x 10^6] / atmospheric pressure
= (0.0015 x 10^6) / 1013
= 1.48 ppm

SVC [mg/m_3] = SVC [ppm] x (molecular weight / 24.04)
= 1.48 x (215.29 / 24.04)
= 13.25 mg/m^3

It was assumed that the airborne concentration of IR3535® will not exceed 1 % of the saturated vapour concentration (CAR IR3535 doc IIB Indirect exposure).

airborne concentration is: 13.25 mg/m^3 x 1% = 0.13 mg/m^3

Inhalation exposure in mg/kg bw/day:

The inhalation rate for long-term exposure is taken into account as the possible exposure time is defined as up to 24 h (conservative assessment).

The systemic dose from inhalation is:

airborne concentration x exposure duration x respiration rate / body weight, which corresponds to:

Adult: (0.13 mg/m^3) x (16 m^3/day) / 60 kg = 0.035 mg/kg bw/day
Child (6-12): (0.13 mg/m^3) x (12 m^3/day) / 23.9 kg = 0.066 mg/kg bw/day
Child (2-6): (0.13 mg/m^3) x (10.1 m^3/day) / 15.6 kg = 0.088 mg/kg bw/day
Toddler: (0.13 mg/m^3) x (8 m^3/day) / 10 kg = 0.11 mg/kg bw/day
Infant: (0.13 mg/m^3) x (5.4 m^3/day) / 8 kg = 0.088 mg/kg bw/day

The exposure to volatized residues is considered negligible.
The exposure by inhalation of volatilized residues after application and the combined inhalative and oral exposure of an adult applying the product on two children and herself/himself are negligible compared to primary (dermal) exposure. Therefore, is not considered on the combined assessment.

Combined scenarios

According to the CAR for IR3535 issued in September 2013 by the Belgian authorities (page 20 of 89), it was agreed not to sum up exposure from the oral route (from hand to mouth, scenario 3) and exposure from the dermal route (primary exposure, evaluated under scenario 1). The oral route (Hand to mouth transfer) not summing by this scenario is not considered to be a significant route of exposure because of bad palatability (bitterness) preventing repeated mouthing by small children and you may not apply to children's hand and adult hand to mouth transfer is only accidental with a minimum hygiene standard.

Combination of scenarios from non-professional exposure and general public are presented:

For adults, combination of scenarios 1 and 2. The inhalation exposure calculated under scenario 2 replaces this calculated under scenario 1. Actually scenario 2 takes into account the multiplication of the number of people to apply the product on to calculate the inhalation exposure.
For infants, toddlers and children, they are not concerned by scenario 2.

Summary table: combined systemic exposure from non-professional uses				
Scenarios combined	**Estimated inhalation uptake (mg/kg bw/day)**	**Estimated dermal uptake (mg/kg bw/day)**	**Estimated oral uptake (mg/kg bw/day)[1]**	**Estimated total uptake (mg/kg bw/day)**
Scenarios [1 and 2]	Adult: 0.013	Adult: 3.57	Included in inhalation uptake	Adult: 3.59

The exposure by inhalation of volatilized residues after application and the combined inhalative and oral exposure of an adult applying the product on two children and herself/himself are negligible compared to primary (dermal) exposure. Scenario 4 not combined since it is considered an overestimation. As already indicated, it is generally agreed that the inhalation route is excluded due to the use outdoors, and because use indoors takes place in the summer in situations where there is a high ventilation rate. It should be noticed that the product is only intended to be used indoors in well ventilated areas or outdoors.

Monitoring data

There are no monitoring data with «Montplet insect repellent IR3535 30%».

Dietary exposure

MONTPLET INSECT REPELLENT IR3535 30% can be applied directly on the skin. The product is applied using hands palms on different parts of the body (hands, arms, head, legs and feet). Human exposure to IR3535 via food is considered to be relevant because IR3535 may be transferred from the treated hands to the food.

Considering that the exposure to repellent residues via food is not negligible, a scenario to estimate the dietary exposure and risk via food is included. This scenario was agreed on at the ARTFood meeting in November 2019 (WGV/2019 HH).

Assumptions

The application rate, expressed as mg of BP per cm^2 of treated skin (mg product/cm^2), is considered to estimate the exposure.
The default values of hand surface that can be in contact with food is expressed as % of the treated body surface. This is equivalent to 100% of hand surface areas for toddler and children, and 50% of hands surface area for adults (Recommendations no. 11 and 14 of the BPC Ad hoc WGHE)
Transfer factor from hand to food: 50 % (default values)
Exposure of all intended age groups
The frequency of hand contact with food should not be included in the calculation.

Refinement

A retention factor of 10% after rinsing can be used to refine exposure if hands are washed after application (default values)

Dietary exposure via food

EXp_{cons} = ApplRate * C * Hfood contact * TF (*RF)/ bw

Where:

EXp_{cons} Dietary exposure (mg a.s./kg bw/d)
ApplRate Application rate (mg product/cm^2) = 0.56 (value given by the efficacy)
C Concentration of a.s. in the BP (%) = 30 %
Hfood contact Hand surface in contact with food (cm^2). (default value)
196.8 cm^2 for infant (<1 year old) (100%)
230.4 cm^2 for toddler (1-2 years old) (100%)
330.9 cm^2 for children (2-6 years old) (100%)
427.8 cm^2 for children (6-12 years old) (100%)
410 cm^2 for adults (50%).

TF % of biocide residue transferred from hands surface to food (default value) 50 %
RF % of biocide residue retained after hands washing = 10% (default value)
bw Body weight (kg) (default value)
8 kg for infant (<1-year-old)
10 kg for toddler (1-2 years old)
15.6 kg for children (2-6 years old)
23.9 kg for children (6-12 years old)
60 kg for adults

Infant Exp_{cons} =
0.56 mg/cm^2 x 30% x 196.8 cm^2 x 50% x 10% / 8 kg = 0.21 mg/kg bw/d

Toddler Exp_{cons} =
0.56 mg/cm^2 x 30% x 230.4 cm^2 x 50% x 10% / 10 kg = 0.19 mg/kg bw/d

Children 2-6 years old Exp_{cons} =
0.56 mg/ cm^2 x 30% x 330.9 cm^2 x 50% x 10% / 15.6 kg = 0.18 mg/kg bw/d

Children 6-12 years old Exp_{cons} =
0.56 mg/ cm^2 x 30% x 427.8 cm^2 x 50% x 10%/ 23.9 kg = 0.15 mg/kg bw/d

Adult Exp_{cons} =
0.56 mg/ cm^2 x 30% x 410 cm^2 x 50% x 10% / 60 kg = 0.06 mg/kg bw/d

the following precautionary advices are recommended:

"Avoid contact of the treated skin or clothes with food."
"Do not use the product near food and surfaces that may come into contact with food and feed or drinks for human consumption"

Information of non-biocidal use of the active substance

IR3535 is only used as a biocide.

Estimating Livestock Exposure to Active Substances used in Biocidal Products

No livestock exposure is foreseen from the use of «Montplet insect repellent IR3535 30%».

Estimating transfer of biocidal active substances into foods as a result of professional and/or industrial application(s)

Not relevant for «Montplet insect repellent IR3535 30%» product.

Estimating transfer of biocidal active substances into foods as a result of non-professional use

Not relevant for «Montplet insect repellent IR3535 30%» product.

Information of non-biocidal use of the active substance
No different use as biocidal PT19 is known for IR3535

Exposure associated with production, formulation and disposal of the biocidal product

During production of the active substance, the whole reaction process (including the loading of raw materials) is carried out in a closed device. Potential human exposure is only possible during loading and cleaning/service processes. Any handling related to these processes are carried out using personal protection measures adapted to each task (up to full personal protection for special cleaning and service tasks).

Formulation of the active substance to produce «MONTPLET INSECT REPELLENT IR3535 30%» is done in modern formulation plants equipped with fully automated equipment. The workers involved in the formulation tasks are trained professional people who usually wear the adequate PPE (according to the task) and their exposure should be negligible.

Aggregated exposure

No aggregated exposure is foreseen.

Summary of exposure assessment

Scenarios and values to be used in risk assessment				
Scenario number	**Exposed group (e.g. professionals, non-professionals, bystanders)**		**Tier /PPE**	**Estimated total uptake (mg/kg bw/d)**
Scenario 1 1 application/day	Non Professionals	Adult	Tier 1/No PPE	3.58
		Children (6-12 years)		4.99
		Children (2-6 years)		5.66
		Toddler (1-2 years)		6.24
		Infant (<1 year)		6.55
Scenario 2 An adult applying on two children and himself	Non professionals	Adult	Tier 1/No PPE	3. 59

Scenarios and values to be used in risk assessment				
Scenario number	**Exposed group (e.g. professionals, non-professionals, bystanders)**		**Tier /PPE**	**Estimated total uptake (mg/kg bw/d)**
Scenario 3 Hand to mouth 1 aplication/day	Non professinals – General public	Adult	Tier 1/No PPE	1.02
		Children (6-12 years)		2.85
		Children (2-6 years)		3.22
		Toddler (1-2 years)		3.55
		Infant (<1 year)		3.79
Scenario 4 Inhalation residues volatil	Non professinals – General public	Adult	Tier 1/No PPE	2.66
		Children (6-12 years)		3.91
		Children (2-6 years)		4.22
		Toddler (1-2 years)		4.68
		Infant (<1 year)		3.31

2.2.6.3 Risk characterisation for human health

Reference values to be used in Risk Characterisation

Reference	Study	NOAEL (LOAEL)	AF[1]	Correction for oral absorption	Value
AELshort-term	1) Rabbit, oral, developmental toxicity study. 2) Rabbit, oral, 28-day toxicity study.	1) NOAEL = 300 mg/kg bw/d 2) NOAEL = 500 mg/kg bw/d	100	100%	5 mg/kg bw/day
AELmedium-term	1) Rabbit, oral, developmental toxicity study. 2) Rabbit, oral, 28-day toxicity study.	1) NOAEL = 300 mg/kg bw/d 2) NOAEL = 500 mg/kg bw/d	100	100%	5 mg/kg bw/day
AELlong-term	1) Rabbit, oral, developmental toxicity study. 2) Rabbit, oral, 28-day toxicity study.	1) NOAEL = 300 mg/kg bw/d 2) NOAEL = 500 mg/kg bw/d	100	100%	5 mg/kg bw/day

[1] Factor 10 for both intra-species and interspecies differences. No extrapolation factor for duration is needed, as the overall NOAEL is derived from a repeated 28d-oral toxicity study and a teratogenicity study.
The derivation of an ADI or an ARfD is not applicable as no residues in food/feed are expected.
No derivation of a local AEC is set in IR3535's CAR based on it is not justified a risk characterisation for local effects.

Maximum residue limits or equivalent
No data available, not relevant.

Risk for industrial users
No relevant, the product is intended to be applied by non-professional users.

Risk for professional users
No relevant, the product is intended to be applied by non-professional users.

Risk for non-professional users

Non-professional users and the general public are gathered in one section for the risk characterisation because people from one population can also be in the other population.

Systemic effects

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL (mg/kg bw/d)	Exposed group	Estimated uptake (mg/kg bw/day)	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Scenario 1 Non professinals	1	1) 300 2) 500	5	Adult	3.58	72	**yes**
				Children (6-12 years)	4.99	99	**yes**
				Children (2-6 years)	5.66	113	**no**
				Toddler (1-2 years)	6.24	125	**no**
				Infant (<1 year)	6.55	133	**no**
Scenario 2 Non professionals	1	1) 300 2) 500	5	Adult	3. 59	72	**yes**
Scenario 3 Non professionals (Public general)	1	1) 300 2) 500	5	Adult	1.02	*	Yes (see below)
				Children (6-12 years)	3.56		
				Children (2-6 years)	4.03		
				Toddler (1-2 years)	4.44		
				Infant (<1 year)	4.74		
Scenario 4 Non professionals (Public general)**	1	1) 300 2) 500	5	Adult	2.66	53	**yes**
				Children (6-12 years)	3.91	78	**yes**
				Children (2-6 years)	4.22	84	**yes**
				Toddler (1-2 years)	4.68	92	**yes**
				Infant (<1 year)	3.31	66	**yes**

** For scenario 4, data obtained with ConsExpo – exposure to vapour – instantaneous release

* For scenario 3, a reverse reference scenario is considered calculating the maximum number of applications which would allow to reach the reference dose:

Reverse reference scenario	Adult	Child (6-2)	Child (2-6)	Toddler	Infant
Oral systemic exposure via hand-mouth transfer mg/kg bw	1.02	3.56	4.03	4.44	4.74
AEL (mg/kg bw /d)	5	5	5	5	5
Oral systemic exposure/AEL Number of time of application b,p before exceeding the AEL via hand-mouth transfer	4,89	1,41	1,24	1,13	1,06

* For scenario 3, a reverse reference scenario is considered calculating the maximum number of applications which would allow to reach the reference dose:
Adult: 5 / 1.02 = 5 applications
Child (6-12): 5 / 3.56 = 1 applications
Child (2-6): 5 / 4.03 = 1 applications
Toddler: 5 / 4.44 = 1 applications
Infant: 5 / 4.74 = 1 applications

As a conclusion for scenario 3, it is recommended that one adult will not apply on more than 5 people (including himself/herself). Actually, he/she is expected not to apply over more than three people (*i.e.* one time himself/herself + two children). No risk via this scenario is expected for adults.
As children will be treated once per day, no risk is expected via the oral route further to hand to mouth exposure after application of 0.56 mg/cm² MONTPLET INSECT REPELLENT IR3535 30%.

The risk is acceptable for **adults** and **children 6-12 years** under all the possible scenarios (1, 2, 3 or 4) if one application is done on the 55% of the body surface area at the dose of 0.56 mg/cm² MONTPLET INSECT REPELLENT IR3535 30% per application.

,
The risk is unacceptable for **children 2-6 years**, **toddlers** and **infants** under the possible scenario 1 one application is done on the 55% of the body surface area at the dose of 0.56 mg/cm² MONTPLET INSECT REPELLENT IR3535 30% per application.

The risk is acceptable for adults and children 6-12 years if one application is done on the 55% of the body surface area at the dose of 0.56 mg/cm² MONTPLET INSECT REPELLENT IR3535 30% per application. This product will not be authorised for infants.

Combined scenarios

Scenarios combined	Tier	Systemic NOAEL (mg/kg bw/d)	AEL (mg/kg bw/d)	Estimated uptake (mg/kg bw/d)	Estimated uptake/ AEL (%)	Acceptable (yes/ no)
1 + 2	1	1) 300 2) 500	5	Adult: 3.59	72	yes

The combined inhalative and oral exposure of an adult applying on two children and herself/himself (scenario 2) are negligible compared to primary (dermal) exposure (from scenario 1). Also, the inhalation of volatised residues should not be combined, since the exposure is calculated for indoor application whilst the product is already authorised only in indoors in well ventilated areas.
No combined scenarios are foreseen.

Dietary exposure

Scenario	Tier	Systemic NOAEL (mg/kg bw/d)	ARfD (mg/kg bw/d)	Estimated exposure (mg/kg bw/d)		Estimated exposure / AEL (%)	Acceptable (yes/ no)
Dietary exposure**	2	500	5	Adult	5,74E-02	1.2	**yes**
				Children (6-12 years)	1,50E-01	3.0	**yes**
				Children (2-6 years)	1,78E-01	3.6	**yes**
				Toddler (1-2 years)	1,94E-01	3.9	**yes**
				Infant (<1 year)	2,07E-01	4.1	**yes**

** the value of the AELacute (Rabbit, overall, developmental study/28-d study: NOAEL of 500 mg/kg/day divided by a standard assessment factor of 100) was used to derive an ARfD of 5 mg/kg bw.

Dietary exposure is acceptable.

the following precautionary advices are recommended:

- "Avoid contact of the treated skin or clothes with food."
- "Do not use the product near food and surfaces that may come into contact with food and feed or drinks for human consumption"

Local effects

Qualitative risk characterization for local effects is required only when the biocidal product is classified for local effects, and triggers classification of the product according to the CLP criteria.

The qualitative risk characterization for MONTPLET INSECT REPELLENT IR3535 30% is performed following the stepwise approach described in the Guidance on the Biocidal Products Regulation, Volume III Human Health - Assessment & Evaluation (Parts B+C) Version 4.0 December 2017. This assessment covers non-professional users and general public.

Local hazard description: The active substance IR3535 is classified as Eye irrit.2; H319. The product MONTPLET INSECT REPELLENT IR3535 30% is classified as Eye irritant. 2. Assignment of hazard categories: Low

- **Qualitative risk assessment for local effects**

Hazard			Exposure						Relevant RMM & PPE	Risk
Hazard category	**Effects in terms of C&L**	**Additional relevant hazard information**	**PT**	**Who is exposed?**	**Tasks, uses, processes**	**Potential exposure route**	**Frequency and duration of potential exposure**	**Rough degree of exposure Degree of potential exposure under best practice conditions**		**Conclusion of risk**
Low	Eye Irrit. 2, H319	IR3535 (30%)	19	General public: adults and children	Application: (Scenarios 1 and 2) See section 2.2.6.2	Skin Eye (splashes, hand to eye transfer)	4 min/day, 90 days/year (summer season when mosquitoes infestations are common) Less than one hour per da	< 5 mg/ kg bw /d Outdoor or indoor in warm season (i.e. efficiently ventilated facilities) spray use	***RMM*** - Labelling, instructions for use that minimise exposure or possible health effects. - The product shall not be sprayed directly to the face, adults will extend the product with their bare hands, and hands will be immediately washed. - Labelling as eye irritant - Do not spray into the eyes or apply to eye area - An adult should apply the product to children below 12 years of age - Do not use on children's hands - Limit the exposure per day to the maximum number of spray-pulses claimed in the label for each human group. - Washing hands after use.	***Acceptable*** + reversible effect. + low likelihood for exposure of eyes. + used with low frequency + short actual exposure. + High ventilation expected, due to its use outdoors and during summer season, where a high ventilated rate is expected indoors + Proper instructions for use, indicating not to spray directly to the face and apply the product on the hand of adults, minimising the hand to eye contact **non-acceptable** Operational and organisational RMMs not applicable Potential children exposure due to hand to eye contact

									- Instructions for use	

Taking into account the appropriate risk mitigation measures considered above, an acceptable risk is expected for local effects (Eye irritation 2) derived from the application of MONTPLET INSECT REPELLENT IR3535 30%.

Authorization of the product is requested, since its use in the period that is intended to be applied (summer time in which mosquitoes proliferate) and the possible effects that mosquitoes can cause in the population (infections, diseases, ...) should be considered much more serious effects compared to the risk to human health arising from the use of the biocidal product in accordance with the proposed conditions of use as follows:
Application rate: 0.56 mg/cm^2. The pump releases a dose of 0.1949 ml (0.1866 g) per spray burst (Applicant data). Please see annex 3.2 for further information
Adults: 5.11 g or aprox. 27 pump strokes
Children (6<12 years): 2.83 g or aprox. 15 pump strokes

Frequency of application: Only one application

Therefore, safe uses are identified for MONTPLET INSECT REPELLENT IR3535 30% for adult and children 6-12 years when the product is applied once per day. There is no safe use for children 2-6 years, toddler. infants.

This argument is based on article 19.5 of the BPR regulation that states that "*Notwithstanding paragraphs 1 and 4, a biocidal product may be authorised when the conditions laid down in paragraph 1(b)(iii) and (iv) are not fully met, or may be authorised for making available on the market for use by the general public when the criteria referred to in paragraph 4(c) are met, where not authorising the biocidal product would result in disproportionate negative impacts for society when compared to the risks to human health, animal health or the environment arising from the use of the biocidal product under the conditions laid down in the authorisation. The use of a biocidal product authorised pursuant to this paragraph shall be subject to appropriate risk mitigation measures to ensure that exposure of humans and the environment to that biocidal product is minimised. The use of a biocidal product authorised pursuant to this paragraph shall be restricted to Member States in which the condition of the first subparagraph is met*."

With regard to the potential risk observed, under systemic effects, an acceptable risk is considered at scenario 1 and 2 for adults and children (6-12 years). In addition, combined scenarios 1+2 shows acceptable exposure for adults. In view of that and considering the risk mitigation measures mentioned on local effects section, an acceptable risk might be expected by the use of the product on for adults and children (6-12 years) skin and an unacceptable risk might be expected by the use of the product on infant skin.

There is no concern for indirect secondary exposure for adults and children (6-12 years) from the use of the biocidal product as a Repellent PT19. Exposure via hand-to-mouth transfer is of minor concern when the product is used as intended (not to be applied to children's hands), and inhalation of volatilized residues after application is limited. Secondary exposure for an adult applying (spraying) the product on two children and herself/himself is minor compared to primary dermal exposure.

Proper use, i.e. use in compliance with correct and complete conditions on the label, of MONTPLET INSECT REPELLENT IR3535 30% is considered safe for adults and children.

The following RMM are required:
Use repellent safely. Always read the label and product information before use.

Suitable for children older than 6 years. Keep out of reach of children. Avoid breathing vapours/spray. Use only outdoors or in a well-ventilated area.
ONLY apply to uncovered parts of the arms, hands, legs, feet and face. For treatment of the face, spray the repellent solution onto the palm of the hand and distribute the solution over the skin of the face thereby taking care to protect the eyes.
Do not spray into the eyes or apply to eye area.
An adult should apply the product to children below 12 years of age.
Do not use on children's hands. Do not apply over cuts, wounds, freshly shaven or irritated skin. Do not use under clothing.
Maximum number of applications per day: once for adults and children above 6-year-old.
Product can be used only for children older than 6 years.
Avoid contact with synthetic materials. Synthetic materials should be protected during spraying and the compatibility with textiles should be tested on a non-visible part of clothes before use.
Applying sun care products or cosmetic formulations after repellent use will decrease the efficacy of the repellent considerably.

MONTPLET INSECT REPELLENT IR3535 30% containing 30% IR3535 can be used one time per day on children 6-12 years and adults.

It is important that the hands of children are not treated to limit the hand to mouth ingestion. The bitterness of the product will also prevent the oral ingestion.

Conclusion

MONTPLET INSECT REPELLENT IR3535 30% pose an unacceptable risk for children 2-6 years, toddler and infant users.

Risk for consumers via residues in food

Not relevant, the product is not intended to be applied on food nor feedstuff.

Risk characterisation from combined exposure to several active substances or substances of concern within a biocidal product

There are no substances of concern
Not relevant, the product is not intended to be applied with other biocidal products.

2.2.7 Risk assessment for animal health

Not applicable. MONTPLET INSECT REPELLENT IR3535 30% is not used on animals and no residues are expected.

2.2.8 Risk assessment for the environment

Please notice that the environmental risk assessment is reported as provided by the applicant. The ES CA position is presented in grey boxes when is needed.

For the product MONTPLET INSECT REPELLENT IR3535 30% no new studies or additional information for the environment have been provided. The active substance contained in this product is the same as evaluated in the CAR for IR3535® and therefore no new data/information on the active substance is required.

This environmental risk assessment was carried out for the biocidal product «Montplet Insect repellent IR3535 30%». This product is an insect repellent (PT19) against mosquitoes containing 30% IR3535 (ethyl butylacetylaminopropionate). The repellent is for use by non-professionnals and is applied as a spray directly to the human skin. It can be used indoors as well as outdoors.

A complete assessment report is available for the active substance IR3535 (AR, March 2014). However, as «Montplet Insect repellent IR3535 30%» differs somewhat in composition and use from the product reprenseted in the IR3535 AR, the risk for the environment was assessed here anew for «Montplet Insect repellent IR3535 30%». The product characteristics that were not covered in the IR3535 AR include:

- The concentration in active substance in the biocidal product. The IR3535 AR was performed considering a maximal active substance concentration of 20%. «Montplet Insect repellent IR3535 30%», however, is composed of 30% IR3535 and is therefore not covered by that scenario.

- Swimming after product application is a scenario that is not covered in the IR3535 AR. Swimming after product application is not restricted for «Montplet Insect repellent IR3535 30%» and this scenario will therefore be taken into account in this risk assessment.

- The ESD for PT19 was not yet published when the IR3535 risk assessment was performed. Environmental risk was previously assessed based on a PT1 (human hygiene) scenario. As the more complete scenario for PT19 is now available, «Montplet Insect repellent IR3535 30%»'s risk assessment will be based on the ESD for PT19.

This environmental risk assessment is based on the information provided in the assessment report for IR3535 (March 2014), including its documents IIb and IIc (provided by the applicant), as well as the "Guidance on the Biocidal Products Regulation, Volume IV Environment – Assessment and evaluation (Parts B+C), Version 2.0" (October 2017) and the "Emission Scenario Document for Product Type 19, Repellents and attractants" (May 2015).

IR3535 forms a known metabolite in water but its ecotoxicity and degradation are covered by the data provided on IR3535 as transformation to the metabolite is very rapid. No SOCs relevant for environmental assessment were identified in the formulation.

2.2.8.1 Effects assessment on the environment

Information relating to the ecotoxicity of the biocidal product which is sufficient to enable a decision to be made concerning the classification of the product is required

Under the CLP classification, the active substance IR3535 is classified as Eye Irrit 2 and the biocidal product «Montplet Insect repellent IR3535 30%» is classified as Eye Irrit 2 and Flam Liq 3. However neither the active substance nor the biocidal product are classified for environmental hazards.

Further Ecotoxicological studies

Product emission to the environment is assumed to mainly affect the STP compartment (via showering) and the aquatic compartment (via swimming in outdoor waterbodies). Acute toxicity studies were carried out for both these compartments in the IR3535 risk assessment and the following endpoints are listed in the active substance AR :

Summary table of effects on aquatic species (most sensitive species of each group)					
Group	**Species**	**Time-scale**	**Endpoint**	**Toxicity**	**Reference**
Fish	Zebra (*Brachydanio rerio*)	96h	LC_{50}	> 100 mg ai/L	AR, 2014
Invertebrates	*Daphnia magna*	48h	EC_{50}	> 100 mg ai/L	
Algae	*Desmodesmus subspicatus*	72h	E_bC_{50} E_rC_{50}	> 100 mg ai/L > 100 mg ai/L	
Microorganisms	*Activated sludge*	3h	EC_{20} EC_{50} EC_{80}	> 1000 mg ai/L > 1000 mg ai/L > 1000 mg ai/L	

Acute toxicity studies carried out on aquatic organisms (*Brachydanio rerio*, *Daphnia magna* and *Desmodesmus subspicatus*) did not indicate a toxic effect of IR3535 and the active substance is therefore not considered toxic for the aquatic environment.

Toxicity in the STP compartment was assessed by observing the inhibition of respiration of sludge microorganisms after 3 hours of contact with the active substance. No inhibitory effect was recorded and IR3535 is not considered toxic for sludge microorganisms.

No studies were carried out in the IR3535 AR for long term aquatic toxicity, marine species or the sediment compartment. Long term aquatic tests were left out because no acute toxicity was recorded for the aquatic compartment. Marine species were not tested because no toxicity was recorded for freshwater species and the marine compartment is not expected to receive any major emissions. As endpoints for these compartments are absent, assessment factors of 1000 for the freshwater compartment and 10 000 for the marine compartment were used. And since no toxicity studies were carried out for the sediment compartment either, the $PNEC_{sed}$ was derived from the $PNEC_{water}$ via the equilibrium partitioning method.

No ecotoxicity studies were carried out for the soil or air compartment in the IR3535 AR. Based on product use, emissions to the soil compartment are expected to be negligible. $PNEC_{soil}$ for the assessment of «Montplet Insect repellent IR3535 30%» was calculated (with EUSES) through the equilibrium partitioning method based on aquatic toxicity data (BPR Guid., Vol. IV Env. Parts B+C, 2017 – p.147). As the active substance has a very low volatility, the air compartment is not expected to be at risk. No PNEC was thus calculated for this compartment.

Conclusion used in Risk Assessment – Further ecotoxicological studies	
Value/conclusion	IR3535 is not considered toxic for the two main receiving compartments (STP compartment and aquatic compartment).
Justification for the value/conclusion	Acute toxicity studies were carried out on fish (*Brachydanio rerio*), *Daphnia magna*, algae (*Desmodesmus subspicatus*) and activated sludge but no toxic effects were observed.

Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk (ADS)

Data waiving	
Information requirement	-
Justification	No data available. Product use and ecotoxicological studies do not suggest possible effects on other specific species.

Supervised trials to assess risks to non-target organisms under field conditions

Data waiving	
Information requirement	-
Justification	No data available. Product use is not expected to pose a risk to non-target organisms. Indeed, the product is applied to human skin which no non-target animals should be in contact with.

Studies on acceptance by ingestion of the biocidal product by any non-target organisms thought to be at risk

Data waiving	
Information requirement	-
Justification	No data available. During product use, ingestion by non-target organisms is not expected to occur as the biocidal product is a repellent applied to human skin.

Secondary ecological effect e.g. when a large proportion of a specific habitat type is treated (ADS)

Data waiving	
Information requirement	-
Justification	No data available. No secondary ecological effects are expected as the biocidal product is a repellent applied to human skin.

Foreseeable routes of entry into the environment on the basis of the use envisaged

Based on the product use, the main entry routes into the environment are the STP compartment (through showering after product application) and the aquatic compartment (through swimming in surface waterbodies). Secondary emission from the STP compartment is expected to affect the aquatic compartments via effluents to surface water and the terrestrial compartments via sludge application to agricultural soil. These secondary emissions are expected to be minor as 99% biodegradation was measured in the STP compartment (AR, 2014).

In the case of emission through swimming, only closed water bodies (lakes, ponds, reservoirs) are considered as a worst-case scenario. Secondary emission from the freshwater compartment is therefore expected to only impact the freshwater sediment. Major impact to the sediment is however not expected as IR3535 remains mainly in the water phase.

The atmosphere compartment is not expected to be affected as IR3535 has low volatility.

Further studies on fate and behaviour in the environment (ADS)

Data waiving	
Information requirement	-
Justification	No data available.

Leaching behaviour (ADS)

Data waiving	
Information requirement	-
Justification	No data available. Risk is not expected for the terrestrial compartment as IR3535 was 99% degraded in the STP.

Testing for distribution and dissipation in soil (ADS)

Distribution

Summary table of the adsorption/desorption in soils								
Method, Guideline, GLP status, Reliability	**Sediment type**	**Adsorbed AS [%]**	**K_a (l/kg)**	**K_{aOC} (l/kg)**	**K_d K_{dOC} K_a/K_d (l/kg)**	**Kf**	**l/n**	**Reference**
	Freshwater	-	9.516	475.25	K_d: 40.4 K_{dOC}: 1136 K_a/K_d: 0.236	-	-	AR, 2014

Conclusion used in Risk Assessment – Further ecotoxicological studies	
Value/conclusion	K_{OC} = 475.25 l/kg
Justification for the value/conclusion	Based on the adsorption/desorption test, a mean (arithmetic) K_{OC} of 475.25 l/kg was determined. DT_{50} in soil was not determined. Only limited exposure is expected for the terrestrial compartment as IR3535 is mainly emitted to STP where it is degraded up to 99%.

Testing for distribution and dissipation in water and sediment (ADS)

Dissipation

Summary table on half lives in water and sediments				
Compartment /process	**DT_{50} measured in test**	**DT_{50} at 12°C**	**Rate constant at 12°C**	**Reference**
Freshwater – aerobic degradation	6.79-8.41 d (20°C)	12.88-15.59 d		AR, 2014

The aerobic water/sediment degradation study from the IR3535 AR indicates that the active substance remains mainly in the water phase. No half-life for the sediment could therefore be determined.

In the water phase, IR3535 is degraded first into its free-acid, which is in its turn degraded. IR3535 degrades rapidly into its metabolite. The subsequent degradation of the free-acid knows two phases: a lag phase, during which degradation is slow, and a rapid ultimate biodegradation phase.

Summary table of identified metabolites /transformation- or reaction products in water and sediments				
Compartment	**Metabolite/ transformation- or reaction product**	**DT_{50} measured in test**	**DT_{50} at 12°C**	**Reference**
Freshwater – aerobic degradation	Free acid (lag phase)	86.1-110 d (20°C)	163.29-208.61 d	AR, 2014
Freshwater – aerobic degradation	Free acid (phase 2, rapid)	4.47-5.68 d (20°C)	8.48-10.77 d	

Conclusion used in Risk Assessment – distribution and dissipation in water and sediment	
Value/conclusion	IR3535 and its free-acid metabolite should not be classified as persistent.
Justification for the value/conclusion	IR3535 remains mainly in the water phase, where it degrades rapidly into its free-acid (DT_{50} (12°C) = 12.88-15.95 days, which is below the P-criterion of 40 days). The free-acid is then ultimately degraded in two phases: a lag phase (DT_{50} (12°C) = 163.29-208.61 days) and a rapid phase (DT_{50} (12°C) = 8.48-10.77 days). These two phases (lag and rapid) are combined together for the P-criterion evaluation and overall DT_{50} values do not indicate that IR3535 is persistent.

Testing for distribution and dissipation in air (ADS)

Data waiving	
Information requirement	-
Justification	Emission of IR3535 to air is unlikely as its vapour pressure is low. IR3535's half-life is 13.16 hours due to reaction with OH-radicals. No accumulation and long range transport in air is therefore expected.

If the biocidal product is to be sprayed near to surface waters then an overspray study may be required to assess risks to aquatic organisms or plants under field conditions (ADS)

Data waiving	
Information requirement	-
Justification	No data available. The product is sprayed on human skin so a risk for overspray is not expected.

Endocrine disrupting properties

Assessment of the ED properties of the active substance:

The biocidal product contains Ethyl butylacetylaminopropionate (IR3535®)
According to the CAR for Ethyl butylacetylaminopropionate (IR3535®) there is no indication for endocrine disrupting properties of the active substance. However, a comprehensive ED-assessment for the active substance and its metabolites according to Regulation (EU) 2017/2100 and the "Revised Guidance Document 150 on Standardised

Test Guidelines for Evaluating Chemicals for Endocrine Disruption" will need to be performed at the renewal stage.

Assessment of the ED properties of non-active substances (co-formulants):

A screening assessment of the endocrine-disrupting properties of the co-formulants in the biocidal product MONTPLET insect repellent IR3535 30% has been performed according to the instructions described in the document agreed in the Coordination Group (CG-34-2019-02 AP 16.5 e-consultation ED potential of co-formulants). Based on existing knowledge and reasonably available scientific information, four co-formulants triggered an alert for ED property (see confidential annex). However, a conclusion has not yet been agreed for these substances and they are still identified as potential EDs. Based on this information, the ES CA considers that the authorisation of the biocidal product MONTPLET INSECT REPELLENT IR3535 30% can proceed. In future, the conclusion of the product could be reconsidered if the conclusion of the ED status of any of these substances would have been agreed.

PNEC derivation

- **STP compartment :**

The PNEC value for the STP compartment was calculated via EUSES and by applying an assessment factor of 100 (BPR Guid. Vol. IV Env. parts B+C – p. 137).

STP compartment PNEC value (mg/l)
$PNEC_{STP}$
> 10

- **Aquatic compartments :**

The PNEC values for the various aquatic compartments were calculated via EUSES.

Summary of the aquatic compartment PNEC values (mg/l)			
$PNEC_{water}$	**$PNEC_{sed}$**	**$PNEC_{seawater}$**	**$PNEC_{seased}$**
> 0.1	> 1.11	> 0.01	> 0.111

- **Terrestrial compartments :**

The PNEC value for the soil compartment was calculated via EUSES. The PNEC value used for the groundwater compartment is a trigger value for pesticides of 0.1 □g/L (BPR Guid. Vol. IV Env. part B+C – p.97)

Summary of the terrestrial compartment PNEC values	
$PNEC_{soil}$	**$PNEC_{groundwater}$**
> 0.85 mg/kg	0.1 g/L

- **Air compartment :**

No PNEC value was calculated for the air compartment as it is not considered relevant in this risk assessment.

- **ES CA:**
- "According to the TGD on Risk Assessment (Table 17, p.109), the PNEC for micro-organisms in a STP is derived by dividing the EC50 from a respiration inhibition test (OECD 209) by a factor of 100 or by dividing the NOEC from a respiration inhibition test by 10. Since no adverse effects were observed in the available test data up to a concentration of 1000 mg/l, both the EC50 as the NOEC are considered to be larger than 1000 mg/l. To derive the PNEC for microorganisms an assessment factor of 10 is used. PNECmicro-organisms (STP) = 100 mg/l"
- Thus, the PNEC for the STP is 100 mg/l.

For the sediment compartment, there are also no toxicity data available. The $PNEC_{sediment}$ was calculated based on equilibrium partitioning method and $PNEC_{water}$.

No terrestrial toxicity tests were performed for IR3535®. Due to the method of application directly on the skin only limited and very local emissions to the soil are expected. IR3535® is not likely to become accumulated in the soil in large amounts. $PNEC_{soil}$ has been calculated based on the equilibrium partitioning method.

The physicochemical properties of IR3535® do not suggest that this substance will pose a risk to the atmospheric environment. Therefore no PNECs were calculated for this compartment.

The low BCF values suggest that IR3535® has a low bioaccumulation potential. Therefore the risk of secondary poisoning via ingestion of contaminated food (eg. earthworms or fish) by birds or mammals is also low and no avian dietary tests were required.

- Sumary of PNEC values:

Summary of PNEC values for the active substance	
Compartment	**PNEC value**
$PNEC_{aquatic}$	> 0.1 mg/l
$PNEC_{sediment}$	> 1.11 mg/kg wwt
$PNEC_{micro\text{-}organisms\ (STP)}$	100 mg/l
$PNEC_{soil}$	> 0.85 mg/kg wwt

-

2.2.8.2 Exposure assessment

General information

Assessed PT	PT 19
Assessed scenarios	*Scenario 1*: Removal through showering and bathing of humans *Scenario 2*: Release to surface waterbodies through swimming
ESD(s) used	Emission Scenario Document for Product Type 19: Repellents and attractants, May 2015
Approach	*Scenario 1*: Average consumption *Scenario 2*: Average consumption
Distribution in the environment	Calculated via : - the EUSES program (EUSES 2.2) - the "Guidance on the Biocidal Products Regulation, Volume IV Environment – Assessment and evaluation (Parts B+C), Version 2.0", October 2017
Groundwater simulation	-
Confidential Annexes	-
Life cycle steps assessed	The "removal of product" step of the product life cycle was assessed for both scenarii

ES CA agrees with the scenarios presented by the applicat.

Emission estimation

Product emission to the environment can occur during the product use (application, service life and removal).

In line with the approach taken in the IR3535 AR (2014), the main emission to the environment is expected to take place during the product removal. After application of the repellent to human skin, product removal can occur through (1) showering or bathing and (2) when swimming in outdoor surface waters. These are the two scenarios that will be taken into account in this risk assessment.

Emission during product application to human skin can also occur as a fraction of the spray can hit the floor or the ground at application. However the TM IV 2013 stated that these emissions are negligible and they are therefore not considered as relevant emission pathways.

The ESD for PT19 also considers emissions during product service life as irrelevant because of IR3535's low volatility.

Scenario 1: Removal through showering and bathing of humans

The first emission pathway is the removal of the insect repellent during showering/bathing of humans. This emission will directly affect sewage treatment plants (STP). Emissions to the STP compartment will then indirectly affect the aquatic compartment (including sediments) via STP effluent. Following the IR3535 AR (2014), virtually no IR3535 is expected to occur in the STP dry sludge so the soil and groundwater compartments are not

expected to be affected by sludge application to agricultural soil. Finally, the air compartment is not expected to be affected due to IR3535's low volatility.

Product emission to the STP compartment was determined via the equation presented in the ESD for PT19. The paramaters in the following table were used as input :

Input parameters for calculating the local emission				
Input		**Value**	**Unit**	**Remarks**
Scenario 1: Removal through showering and bathing of humans				
N_{local}	Number of inhabitants feeding one sewage treatment plant	10 000	-	Default value from ESD
$Cform_{weight}$	Active substance in the product	300	g/kg	30% a.s.
$Qform_{appl}$	Consumption per application	0.56	mg/cm²	Data from efficacy studies
$AREA_{skin}$	Treated area of human skin	9130	cm²	ESD for PT19 and TAB Environment (ENV 172)
N_{appl}	Number of applications per day	1	d^{-1}	Proposed value from ESD based on product efficacy (9 hours efficacy) and in line with the human health RA
F_{water}	Fraction released to wastewater	1	-	Worst-case value from ESD
F_{inh}	Fraction of inhabitants using a repellent product	0.2	-	Default value in ESD for use as repellent on human skin
F_{penetr}	Market share of repellent	0.5	-	Default value from ESD

In line with the efficacy studies, an application rate of 0.56 mg/cm² is used. According to the ESD for PT19 and to the TAB Environment (ENV 172), the treated skin area to be considered for a standard adult person is 9130 cm². The product can also be applied on children, but considering adults is a worst-case scenario, since the area of skin and the maximal number of daily applications are higher for adults than for children.

The number of product applications per day (N_{appl}) was set to 1, as it is the maximum indicated in the authorised uses section.

The fraction of product that is released to the wastewater (F_{water}) will vary depending on the amount of product that evaporates from the skin or that is dermally absorbed. IR3535 has low volatility and is thus not expected to evaporate. The IR3535 AR indicates that a fraction of the active substance can be dermally absorbed. However, a worst-case scenario was considered here and F_{water} was set to 1 (indicating that the entirety of the product is released to the wastewater).

The following equation from the ESD for PT19 was used to calculate the product emission to the STP compartment :

Local emission rate to wastewater ($Elocal_{STP}$):
$Elocal_{STP}$

$$= N_{local} * N_{appl} * Qform_{appl} * AREA_{skin} * Cform_{weight} * F_{inh} * F_{water} * F_{penetr} * 10^{-9}$$

= 10 000 * 1 * 0.56 * 9130 * 300 * 0.2 * 1 * 0.5 * 10^{-9}

= 1.53 kg/day

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Remarks**
STP	1.53	-

Scenario 2: Release to surface waterbodies through swimming

The second emission pathway is removal of the insect repellent through swimming in outdoor surface waters. As opposed to the first scenario, product release through outdoor swimming will bypass the STP compartment and be directly released to surface waterbodies.

As proposed by the ESD for PT19, only ponds, lakes and reservoirs are considered in this scenario. Indeed, they represent a worst-case scenario as dilution is expected to occur when swimming in flowing waters (freshwater rivers or coastal areas). The only affected compartments will therefore be the freshwater compartment and its corresponding sediment compartment.

Product emission to the freshwater compartment was determined via the equation presented in the ESD for PT19. The paramaters in the following table were used as input :

Input parameters for calculating the local emission				
Input		**Value**	**Unit**	**Remarks**
Scenario 2: Release to surface waterbodies through swimming				
$N_{swimmers}$	Daily number of swimmers	1500	-	Default value from ESD
F_{swim}	Fraction of swimmers using the repellent product	0.1	-	Default value from ESD for product authorization
N_{appl}	Number of applications per day	1	d^{-1}	Default value from ESD (not based on product efficacy as application is expected only once before swimming)
$F_{waterbody}$	Fraction released to surface water body	1	-	Default value from ESD
$Cform_{weight}$	Active substance in the product	300	g/kg	30% a.s.
$Qform_{appl}$	Consumption per application	0.56	mg/cm²	Data from efficacy studies
$AREA_{skin}$	Treated area of human skin	9130	cm²	ESD for PT19 and TAB Environment (ENV 172)

The same values were used for the variable paramaters as in the first scenario (consumption per application, treated area of human skin and fraction of product released to surface water body), except for the number of product applications before release. As stated in the ESD for PT19, repellent application is only expected to occur once before swimming.

The following equation from the ESD for PT19 was used to calculate the product emission to the freshwater compartment :

Local emission rate to surface water ($Elocal_{water}$):
$Elocal_{water}$

$= N_{swimmer} * N_{appl} * Qform_{appl} * AREA_{skin} * Cform_{weight} * F_{swim} * F_{waterbody} * 10^{-9}$

$= 1500 * 1 * 0.56 * 9130 * 300 * 0.1 * 1 * 10^{-9}$

= 0.23 kg/day

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Remarks**
Freshwater	0.23	-

Fate and distribution in exposed environmental compartments

Identification of relevant receiving compartments based on the exposure pathway									
	Fresh-water	Freshwater sediment	Sea-water	Seawater sediment	STP	Air	Soil	Ground-water	Other
Scenario 1	Yes	yes	yes	yes	yes	no	yes	yes	-
Scenario 2	Yes	yes	no	no	no	no	no	no	-

The compartments receiving product emission vary between the two scenarios. The air compartment is not expected to be affected in either scenario due to IR3535's low volatility.

In the case of product release through showering/bathing (scenario 1), the main receiving compartment is the STP as product is washed off into wastewater. From there on, indirect emissions can occur from the STP to the freshwater compartment (via STP effluents) and to the soil compartment (via STP sludge application to agricultural soil). In the first case, freshwater sediments as well as the marine compartment can then be affected. In the second, product release can occur from the soil and affect the groundwater compartment.

In the case of product release through outdoor swimming (scenario 2), the main receiving compartment is the freshwater as the product is washed off into ponds, lakes or reservoirs. Freshwater and its corresponding sediment compartment are the only affected compartments. Indeed, product emission bypasses the STP compartment and, due to dilution effects, emissions to rivers or the marine compartment are considered covered by the lakes, ponds etc. as a worst-case.

The EUSES program was used for calculating certain parts of the product distribution in the environment. The following data extracted from the IR3535 AR served as input paramaters in EUSES :

Input parameters (only set values) for calculating the fate and distribution in the environment			
Input	**Value**	**Unit**	**Remarks**
Molecular weight	215.29	g/mol	-

Melting point	-90	°C	-
Boiling point	300	°C	-
Vapour pressure (at 20°C)	0.15	Pa	-
Water solubility (at 20°C)	7×10^4	mg/l	-
Log Octanol/water partition coefficient	1.7	Log 10	-
Organic carbon/water partition coefficient (Koc)	475.25	l/kg	-
Biodegradability	Not readily biodegradable	-	Not readily biodegradable according to two "ready tests". However, an STP simulation test indicated > 99% elimination after 28 days.
Henry's law constant (at 20°C)	4.613×10^{-4}	$Pa.m^3/mol$	-
Use or bypass STP (local marine assessment)	Use STP	-	As indicated in the BPR Guid. Vol. IV Env. Parts B+C (2017) – p.107, for substances that are for private or public use (versus industrial use) it can be assumed that the degree of treatment in a biological STP corresponds to the inland scenario.

In the case of scenario 1, the product can be redistributed into secondary compartments after entering the STP compartment. In the first tier approach of the IR3535 AR, IR3535 is regarded as non-biodegradable and the entirety of the product emission to the STP compartement is redistributed into the secondary compartments. With this approach, IR3535 failed to pass the environmental risk assessment in the IR3535 AR. The risk was therefore evaluated once again with a second tier approach, where active substace biodegradation was taken into account. Indeed, 99% of IR3535 elimination was measured in a STP simulation test and this value was therefore used for the second tier approach (as agreed at the TM IV 2010).

As the risk assessment for IR3535 failed for a first tier approach and since «Montplet Insect repellent IR3535 30%» has a higher risk level (due to a higher concentration in active substance), it was decided to directly apply the second tier approach of the IR3535 AR (2014). Biodegradation in the STP was therefore set at 99% and the remaining 1% enters the water compartment. The final redistribution from the STP compartment is indicated in the following table :

Calculated fate and distribution in the STP			
Compartment	Percentage [%]		Remarks
	Scenario 1	Scenario 2	
Air	0	-	Emissions to air are considered negligible due to the low vapour pressure of the active substance (0.15 Pa) (AR, 2014)
Water	1	-	AR, 2014
Sludge	0	-	
Degraded in STP	99	-	Based on the STP simulation test (AR, 2014)

ES CA: ES CA agrees with the applicant's comments. We consider more convenient apply directly the second tier approach.

Calculated PEC values

Summary table on calculated PEC values								
	PEC_{STP}	**PEC_{water}**	**PEC_{sed}**	**$PEC_{seawater}$**	**PEC_{seased}**	**PEC_{soil}**	**PEC_{GW}**	**PEC_{air}**
	[mg/l]	[mg/l]	[mg/kg_{wwt}]	[mg/l]	[mg/kg_{wwt}]	[mg/kg_{wwt}]	[□g/l]	[mg/m^3]
Scenario 1	7.65 x 10^{-3}	7.65 x 10^{-4}	8.5 x 10^{-3}	7.65 x 10^{-5}	8.5 x 10^{-4}	-	-	-
Scenario 2	-	0.048	0.535	-	-	-	-	-

Scenario 1: Removal through showering and bathing of humans

- **PEC in STP by direct product release to STP:**

The PEC_{STP} was calculated following the BPR Guid. Vol. IV Env. Parts B+C (2017) – p. 72. The following equations and input values were used :

Concentration in untreated water ($C_{local,inf}$) :

$$Clocal,\inf = \frac{Elocal,water \times 10^6}{EFFLUENTstp}$$

= 1.53 * 10^6 / 2 x 10^6

= 0.765 mg/l

Concentration of substance in the STP effluent ($C_{local,eff}$ = PEC_{STP}) :

$$Clocal,eff = Clocal,\inf \times Fstp,water$$

= 0.765 * 0.01

= 7.65 x 10^{-3} mg/l

Input parameters for calculating PEC_{STP}				
Input		**Value**	**Unit**	**Remarks**
$E_{local,water}$	Local emission rate to (waste) water during episode	1.53	kg/day	Calculated in previous step
$EFFLUENT_{STP}$	Effluent discharge rate of STP	2 x 10^6	l/day	Default value in Guidance
$F_{STP,water}$	Fraction of emission directed to water by STP	0.01	-	Calculated in previous step

EUSES 2.2 has an scenario for PT19. When applying the scenario for PT19 in EUSES with the following input values, the same PEC_{STP} value was obtained as via the manual calculations above :

EUSES input parameters – Aerosol spray scenario			
Input	**Value**	**Unit**	**Remarks**

Fraction of inhabitants using the product	0.2	-	Default value from ESD
Number of applications	1	-	Proposed value from ESD based on product efficacy (9 hours efficacy)
Consumption per application	5.11	g	Output ($Qform_{appl}$ * $AREA_{skin}$)
Active substance in product	30	%	-

- **PEC in freshwater / freshwater sediment / seawater / seawater sediment, by release from STP:**

The EUSES program automatically calculates the PEC values for these compartments. This data was therefore taken from the EUSES outputs.

- **PEC in soil / groundwater, by release from STP:**

In view of the redistribution in the STP compartment, no IR3535 is expected to accumulate in the STP dry sludge. The soil and groundwater compartments are therefore not expected to be affected and no PEC_{soil} or PEC_{GW} were calculated.

Scenario 2: Release to surface waterbodies through swimming

There are no options in the EUSES program to run the outdoors swimming scenario. Therefore both PEC values were estimated by following the ECHA guidances.

- **PEC in freshwater by direct product release to surface waterbodies:**

The PEC_{water} was estimated based on equations indicated in the ESD for PT19. The following data was used as input paramaters:

Input parameters for calculating the local PEC_{water}				
Input		**Value**	**Unit**	**Remarks**
Scenario 2: Release to surface waterbodies through swimming				
$Elocal_{water}$	Local emission rate to surface water body	0.23	kg/day	Output from previous emission estimation
$V_{waterbody}$	Volume of water body	435 000	m^3	Default value from ESD
$T_{emission}$	Number of emission days	91	days	Product use only takes place during 3 months of peak bug season (as proposed in ESD)

As a first tier approach, the PEC_{water} corresponds to the $Clocal_{water}$. The following equation was therefore used to estimate PEC_{water} :

Local concentration in water body over 91 days ($Clocal_{water, 91d}$):
$Clocal_{water, 91d}$

$= 10^3 * Elocal_{water} * T_{emission} / V_{waterbody}$

$= 10^3 * 0.23 * 91 / 435\,000$

$= 0.048$ mg/L

- **PEC in freshwater sediment by release from freshwater:**

This PEC was obtained by following the methods in the BPR Guid.Vol. IV Env. parts B+C – p.84, where the PEC_{sed} can be estimated via the following equation and input paramaters:

$$PEClocal,sed = \frac{Ksusp,wat}{RHOsusp} \times PEClocal,water \times 1000$$

= 12.8 / 1150 * 0.048 * 1000

= 0.535 mg/kg

Input parameters for calculating the local PEC_{sed}				
Input		**Value**	**Unit**	**Remarks**
$PEC_{local,water}$	Concentration in surface water during emission episode	0.048	mg/l	Calculated via EUSES
RHO_{susp}	Bulk density of suspended matter	1150	kg/m^3	Standard value from BPR Guid. Vol. IV Env. parts B+C – p.53
$K_{susp,water}$	Suspended matter-water partitioning coefficient	12.8	m^3/m^3	Calculated via EUSES

Primary and secondary poisoning

As stated in the IR3535 AR, poisoning is not considered relevant. Primary poisoning should not occur as product use does not result in direct exposure for birds and mammals. Risk through secondary poisoning is also low since IR3535 has a low potential for bioaccumulation (with Log P_{OW} = 1.7) and a low potential for bioconcentration in the food chain (BCF_{fish} = 5.6 l/kg and $BCF_{earthworm}$ = 1.44 kg/kg).

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2.2.8.3 Risk characterisation

Atmosphere

Conclusion:
Product emission to air is not considered relevant due to IR3535's low vapour pressure (0.15 Pa at 20°C). No risk is therefore expected for the air compartment.

Sewage treatment plant (STP)

Summary table on calculated PEC/PNEC values	
	$PEC/PNEC_{STP}$
Scenario 1	< 7.65 x 10^{-4}
Scenario 2	-

Conclusion:
In the case of scenario 1, the entire fraction of the applied product is emitted to the STP compartment. However, the IR3535 AR indicated 99% of active substance elimination during an STP simulation test and scenario 1 has an acceptable PEC/PNEC ratio. No unacceptable risk was therefore identified for microorganisms.

In the case of scenario 2, no emissions are expected towards the STP compartment.

ESCA:

As it has been indicated above, $PNEC_{STP}$ is 100 mg/L instead of 10 mg/L so the $PEC/PNEC_{STP}$ value should be < 7.65 x 10^{-3} instead of the value calculated by the applicant, nevertheless, this change does not modify the conclusion of the assessment. Thus, we agree with the conclusion of the applicant.

Aquatic compartment

Summary table on calculated PEC/PNEC values				
	$PEC/PNEC_{water}$	**$PEC/PNEC_{sed}$**	**$PEC/PNEC_{seawater}$**	**$PEC/PNEC_{seased}$**
Scenario 1	< 7.65 x 10^{-3}	< 7.65 x 10^{-3}	< 7.65 x 10^{-3}	< 7.65 x 10^{-3}
Scenario 2	< 0.48	< 0.48	-	-

Conclusion:
In the case of scenario 1, the aquatic compartment is not the main receiving compartment. Only a fraction of the active substance is emitted to the freshwater compartment (1%) since 99% is degraded in the STP compartment. For the fraction that is emitted in the freshwater compartment, the PEC/PNEC ratio indicates no unacceptable risks for freshwater organisms. The freshwater PEC/PNEC ratio also covers the freshwater sediment and marine compartments (no toxicity data is available for the sediment and marine compartments and the PNECS were calculated based on the equilibrium partitioning method).

In the case of scenario 2, product emission is only considered for lakes/ponds/reservoirs so only the freshwater compartments are concerned. Freshwater is the main receiving compartment for this scenario as a worst-case scenario considers that the entire fraction of product applied is released to freshwater through swimming. In these conditions, the risk is unacceptable for freshwater and sediments. Further refinements and/or risk mitigation measures would be necessary to make this risk acceptable.

ES CA do not agree with the conclusions given by the applicant for scenario 2. Given the results of PEC/PNEC, the risk in scenario 2 is acceptable for both freshwater and sediments.

Terrestrial compartment

Calculated PEC/PNEC values	
	$PEC/PNEC_{soil}$
Scenario 1	-
Scenario 2	-

Conclusion:
In the case of scenario 1, the soil compartment is not expected to be affected by secondary exposure as no IR3535 accumulates in the dry sludge.

In the case of scenario 2, no emissions are expected to the soil compartment.

ES CA agrees with the conclusion given by the applicant.

Groundwater

Calculated PEC/PNEC values	
	PEC/PNEC$_{gw}$
Scenario 1	-
Scenario 2	-

Conclusion:
In the case of scenario 1, since no product enters the soil compartment, no risk is expected for the groundwater compartment either.

In the case of scenario 2, no emission is expected to the groundwater compartment.

ES CA agrees with the conclusion given by the applicant.

Primary and secondary poisoning

As stated in the IR3535 AR, poisoning is not considered relevant. Primary poisoning should not occur as product use does not result in direct exposure for birds and mammals. Risk through secondary poisoning is also low since IR3535 has a low potential for bioaccumulation (with Log P_{OW} = 1.7) and a low potential for bioconcentration in the food chain (BCF_{fish} = 5.6 l/kg and $BCF_{earthworm}$ = 1.44 kg/kg).

ES CA agrees with the conclusion given by the applicant.

Overall conclusion on the risk assessment for the environment of the product
Two scenarios were considered in this risk assessment. No unacceptable risk was identified for scenario 1, i.e. when emissions occur following the showering/bathing of the users. For scenario 2, i.e. when the emissions occur through outdoor swimming in surface water bodies, the risk for surface water and sediments is unacceptable. The overall risk for the environment is thus not acceptable. Further refinements and/or risk mitigation measures should be applied to make this risk acceptable.

ES CA do not agree with the conclusion given by the applicant.
Based on this risk assessment and on available data, «Montplet Insect repellent IR3535 30%» should not cause any unacceptable risks to the environment.

2.2.9 Measures to protect man, animals and the environment

Please refer to summary of the product assessment and to the relevant sections of the assessment report.

2.2.10 Assessment of a combination of biocidal products

Not relevant. The formulation is not intended to be used in combination with any other biocidal product.

2.2.11 Comparative assessment

Not relevant.

3 ANNEXES[2]

3.1 List of studies for the biocidal product

Author	Year	Title	Report no.	Owner company
[redacted]	[redacted]	SHELF-LIFE STABILITY STUDY AT 25°C/60%RH FOR 3 YEARS ON THE TEST ITEM "MONTPLET INSECT REPELLENT IR3535 30%"	2017/201 AM	Alcoholes Montplet
[redacted]	[redacted]	Accelerated stability study at 30°C for 18 weeks on the test item "Montplet insect repellent IR3535 30%"	2017/200 AM	Alcoholes Montplet
[redacted]	[redacted]	Acute dermal toxicity on repelente insectos forte montplet	2012/1085 AM	Alcoholes Montplet
[redacted]	[redacted]	Determination of the surface tension (SFT) of a liquid. Wilhelmy plate method	IN-01232/2020-3	Laboratorios Montplet
[redacted]	[redacted]	Determinación del punto de inflamación en copa cerrada	A8111	Alcoholes Montplet
[redacted]	[redacted]	Viscosity	19-0328.03	Laboratorios Montplet
[redacted]	[redacted]	Validation of an HPLC-UV method for the quantification of ethyl butylacetylaminopropionate (IR3535®) active ingredient in the test item "Montplet Insect Repellent IR3535 30%"	S-2017-02130 AM	Eurofins

3.2 Output tables from exposure assessment tools

Risk assessment for human health

MONTPLET 30
Human Exposure cal

Dose Calculation

	Adult	Child (6 to < 12 years old)	Child (2 to < 6 years old)	Toddler	Infant
Area to be treated (cm2)	9130	5060	3740	2640	2255
Dose per exposed area (mg)	5112,80	2833,60	2094,40	1478,40	1262,80
Dose per exposed area (g)	5,11	2,83	2,09	1,48	1,26
Density (g/ml)	0,9574	0,9574	0,9574	0,9574	0,9574
Dose per exposed area (ml)	5,3403	2,9597	2,1876	1,5442	1,3190
Pump dose (ml)	0,1949	0,1949	0,1949	0,1949	0,1949
Number of strokes	27	15	11	8	7

Risk assessment for the environment (output tables from Euses)

EUSES_MONTPLET
INSECT REPELLENT 3

3.3 New information on the active substance

New information on the active substance is not available.

3.4 Residue behaviour

No residues of the product in food or feed occur.

3.5 Summaries of the efficacy studies (B.5.10.1-xx)[3]

Please, see section 2.2.5.5

3.6 Confidential annex

See PAR confidential